U.S. Department
of Transportation
**National Highway
Traffic Safety
Administration**

Potential for Application of Corneal Retinal Potential Measurements to Detect Alcohol and Drug Use:

A Report to Congress
May 1988

Prepared in Response to: Section 203:
P.L. 100-17; April 1987
Highway Safety Act of 1987

Technical Report Documentation Page

1. Report No.	2. Government Accession No.	3. Recipient's Catalog No.
DOT HS 807 282		

4. Title and Subtitle	5. Report Date
Potential for Application of Corneal Retinal Potential Measurements to Detect Alcohol and Drug Use: A Report to Congress	May 1988
	6. Performing Organization Code
	8. Performing Organization Report No.
7. Author(s) Alfred J. Farina	
9. Performing Organization Name and Address National Highway Traffic Safety Administration Research and Development Office of Driver and Pedestrian Research	10. Work Unit No. (TRAIS)
	11. Contract or Grant No.
	13. Type of Report and Period Covered
12. Sponsoring Agency Name and Address National Highway Traffic Safety Administration 400 Seventh Street, S.W. Washington, DC 20590	14. Sponsoring Agency Code

15. Supplementary Notes
This report was prepared by the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) in response to Section 203 of the Highway Safety Act of 1987 (P.L. 100-17; April 1987)

16. Abstract

Congress authorized the Secretary of Transportation to: "...test a new drug and alcohol testing technology which measures corneal retinal potential as exhibited in the brain function wave form...to determine the potential for applying such technology and devices in preventing drug and alcohol related traffic deaths." This new technology resides in a single commercial device which the NHTSA arranged to test. However, the device continues to undergo development and a lapse in its scheduling prevented any testing by the government in time for this report. Consequently, NHTSA's examination is based upon a review of existing data and information provided by the developers rather than an active test of the technology.

The report centers on three questions which underlie the new technology:

- **Do drugs and alcohol present characteristic "signatures" in the electronystagmograph (ENG) waveforms?**
- **Can human experts read these signatures and make reliable and valid diagnoses based on them?**
- **Can the human experts' diagnostic skills be computerized to permit widespread application of the technology?**

Additional issues covered include the developmental needs of this technology, and its potential role in highway safety.

17. Key Words	18. Distribution Statement
drug detection, corneal retinal potential, drugs, drugs and driving, highway safety	Document is available to the public through the National Technical Information Service, Springfield, VA

19. Security Classif. (of this report)	20. Security Classif. (of this page)	21. No. of Pages	22. Price

Form DOT F 1700.7 (8-72) Reproduction of completed page authorized

EXECUTIVE SUMMARY

In Section 203 of Public Law 100-17 of the Highway Safety Act of 1987, Congress authorized the Secretary of Transportation to:

> ...test a new drug and alcohol testing technology which measures corneal retinal potential as exhibited in the brain function wave form...to determine the potential for applying such technology and devices in preventing drug and alcohol related traffic deaths.

This new technology resides in a single commercial device which the National Highway Traffic Safety Administration (NHTSA) arranged to test in response to Congress's request. However, the device continues to undergo development and a lapse in its scheduling prevented any testing by the government in time for this report. Consequently, NHTSA's examination is based upon a review of existing data and information provided by the developers rather than an active test of the technology.

Technical Background

The term "corneal retinal potential" refers to an electrical difference ("potential") existing between the cornea and the retina of the eye. This potential creates an electrical field in front of the face that changes as the eyeballs rotate. Medical research has determined that this potential is affected by the functioning of the body's balance system made up of the eyes, the brain, and the skeletal muscles that maintain a person in an upright position. The corneal retinal potential produced by eye movements can be measured and recorded with an electronystagmograph (ENG). Physicians have used the ENG for decades to diagnose balance disorders.

Recently, the ENG has been suggested as a tool for identifying persons who are under the influence of alcohol and drugs, since these substances may affect man's balance system.

Balance tests have long been used to detect alcohol intoxication. Research sponsored by NHTSA produced a battery of sobriety tests for use at roadside by law enforcement officers. Two of the three tests (One-Leg Stand, and Walk and Turn) directly involve balance (in the context of a divided-attention task) while the third--Gaze Nystagmus--refers to a particular kind of eye movement indicative of intoxication. Thus, balance and eye movements are already used to detect the use of a common drug -- alcohol.

As other drugs were recognized as a health problem, attention turned to an intriguing question: could the ENG be used to make reliable identifications of various drugs?

Veritas™ 100 Analyzer

Through the continuing efforts of two researchers, and the commercial backing of a large corporation, a computerized ENG measurement device -- the Veritas™ 100 Analyzer -- is being developed to detect various drugs. The Veritas™ amplifies and analyzes corneal retinal potentials (CRPs) produced by the eyes. The device is intended to do several tasks automatically. These include presenting a standard testing situation to a person suspected of being under the influence of alcohol and/or drugs; recording the CRP responses of the subject; analyzing the CRP waveforms for the presence of drug or alcohol "signatures"; providing a written diagnosis of the person's drug or alcohol state; and, retaining a permanent record of the test results. The manufacturer estimates that this takes a total of about five minutes.

The prototype Veritas™ is about the size of a typewriter, weighs 35 pounds, has a keyboard for data entry, and displays test instructions and results on a CRT screen. A built-in printer provides hard copy of the results while the ENG waveforms are recorded on a floppy disk. The subject is connected to the device by wearing a disposable headband containing flat electrodes. The manufacturer asserts that the advantages of the technology are that the process is not physically invasive, requires no drawing of bodily fluids, and detects a variety of drugs and alcohol at one time (though the question of detecting combinations of drugs remains untested). It does, however, require the full cooperation (e.g., moving eyes --both opened and closed-- to extreme positions while both seated and lying supine) of the person being tested, a feature that could present severe problems in the field.

However, the Veritas™ device is not yet at a stage where it can do all that is expected of it. In particular, computer programs to identify various drug signatures have not yet been developed or tested. Each drug family (hallucinogens, cocaine, tranquilizers, barbiturates, opiates, alcohol, amphetamines, and marijuana) requires a separate program or "algorithm" to be developed and validated. At the present time, an algorithm has been developed and tested for alcohol and a cocaine algorithm is nearing completion. Other parts of a total system are also lacking. Hardware development problems exist; these led to the delay of NHTSA's field test of the alcohol algorithm.

Since the device itself cannot yet be tested in the field, this report is based on the work which led to its development.

Research Review

The research evidence reviewed consisted of several published research articles supplemented in some instances by computer printouts of supporting test data, and information provided by the researchers in response to NHTSA's requests. Background information was also obtained from a Veritas™ Training Manual and a Prosecutor's Guide (both draft versions). NHTSA staff personnel visited the offices of National Patent Analytical Systems, Inc., the development corporation for the Veritas™ device, and conferred with the research staff, who were most cooperative.

It should be noted that the research articles, which form the bulk of the materials upon which this report is based, generally did not meet accepted standards of research reporting. Descriptions of how the work was conducted were incomplete, and insufficient data were provided to permit a reader to check on the results and conclusions. Gaps in the articles were frequently resolved only by contacting the authors directly. The research does show improvement over time. The early work uses all available data to explore whether the drug and alcohol signature concept exists. A pool of ENG waveforms (2,000 or so cases) was developed, but it is uncertain whether the published reports make repeated use of the same cases or whether new cases are being reported on. More recent research moved away from use of accidental samples (surgical candidates and patients) to more purposive data-collection efforts, and adheres more closely to double-blind procedures and fixed test protocols. Nonetheless, all of the research has been done by the developers with no independent verification. The technical shortcomings of the reported research create an unfortunate barrier to ready acceptance of the ENG technology.

The research review centered on three questions which underlie the new technology:

1) Do drugs and alcohol present characteristic "signatures" in the ENG waveforms?

2) Can human experts read these signatures and make reliable and valid diagnoses based on them?

3) Can the human experts' diagnostic skills be computerized to permit widespread application of the technology?

Our findings on these questions follow:

1. Do drugs and alcohol create characteristic "signatures" in the ENG waveforms?

This question is relevant, as Veritas™ claims to detect drug and alcohol presence by analyzing these signatures. The original research identifying the signatures is flawed by the presence of several factors in the experimental subjects which might affect the emergence of a typical signature. These include long-term versus short-term use of the drug being tested, the presence of a medical condition requiring the drug, and, for some subjects, being under anesthesia when tested. Some of these problems are corrected in later research. These issues aside, it is clear that the signatures, if they exist, consist of relatively subtle and complex differences in the ENG waveforms. They cannot be detected readily by untrained observers. The Veritas™ developers estimate that months of training, equivalent to that needed to read electrocardiograms, would be required to learn to read the ENG waveforms. Only two people -- the Veritas™ developers themselves -- are presently trained to read them. It is unlikely that the existence of these waveforms will be tested by

independent researchers in the near future. Even if they do exist, the key question is whether they can be used to identify drug presence. This leads to the second question.

2. Can human experts read these signatures and make reliable and valid diagnoses based on them?

The evidence presented by the Veritas™ developers suggests that they can. Better experimental control is demonstrated in the supporting research. Double-blind procedures are used along with placebo conditions. Drug-free subjects are used, with baseline testing being followed by drug testing, thus permitting before-after comparisons. A 1984 research article addressed the question of the experts' skill at reading the drug and alcohol signatures, but provided no quantitative data to support the positive findings. Data were presented in later papers which do speak to the experts' diagnostic skills. Supported by two major data sets, they correctly identify a wide range of drugs in over 90 percent of the subjects tested. These results are encouraging, but if highly-trained experts are required to detect drugs and alcohol in ENG waveforms, then widespread application and benefit to highway safety are unlikely. The process would be much more useful if it could be automated and made widely available.

3. Can the human experts' diagnostic skills be computerized to permit widespread application of the technology?

The Veritas™ developers have produced and tested one algorithm, for alcohol. Based on their test results, the alcohol algorithm appears to work well. It mimics the experts' judgments in both correct and incorrect diagnoses. As shown in the NHTSA report, the algorithm identified alcohol-free subjects nearly 100 percent of the time, regardless of whether or not other drugs are present. Similarly, the algorithm identified subjects with high blood alcohol levels (a blood alcohol concentration above 0.10% weight/volume -- the legal blood alcohol limit in most states) more than 90 percent of the time. The algorithm (and the human experts) had difficulty identifying subjects with lower blood alcohol (less than 0.05%), but identification improved as the blood alcohol levels increased. No algorithms for drugs other than alcohol have been developed to the point where they can be tested.

Additional Issues

The research review focused on the origins and supporting research of the ENG technology. In addressing Congress's concern about the potential of this technology, it was appropriate also to look ahead at the work that remains to be done, and how a Veritas™ device might be used in the traffic law enforcement area.

Further work for the Veritas™ device that would move it from the laboratory into the field includes developing and testing of diagnostic algorithms for drugs other than alcohol, testing the algorithms at independent sites, producing field-ready equipment, providing training and support to users, and addressing legal issues.

The principal role seen for the device is in identifying drugs which would warrant further actions by the police, e.g., seeking quantitative evidence. Significant legal requirements must be met before Veritas™ could perform this function. Its scientific rationale must be accepted by the courts so that the tests would be admissible evidence. Implied consent laws may need to be amended to include tests dealing with ENG waveforms. In the quite distant future, Veritas™ might conceivably serve a role like that of the breathalyzer machine today, but a significant amount of research on drugs and traffic safety needs to be done before this role could be seriously considered . The state of knowledge in the drug-traffic safety area does not approach that of the alcohol-traffic safety area, and this knowledge gap will act to limit the acceptance of drug-identification devices at this level.

Conclusions

- Balance and eye movements are already used to detect the use of a common drug -- alcohol. Current field alcohol sobriety tests are based on observing balance (within a divided-attention task) and eye movements.

- The foundations of the ENG technology appear sound, having been developed over decades of use by physicians in the diagnosis of balance disorders.

- There is indirect evidence that various families of drugs (including alcohol) produce unique drug evoked potentials or "signatures" in ENG waveforms as evidenced by the fact that trained experts can identify different drugs through these signatures.

- It appears likely that computer algorithms could be developed to identify certain drugs through ENG waveforms. This critical step is necessary for the technology to be widely used. An algorithm has been developed for alcohol, but performance tests of this algorithm have been limited.

- There is insufficient practical evidence to judge whether or not the ENG technology can be useful in field drug and alcohol detection. The additional steps necessary before an assessment can be made include:

  -- Develop algorithms for important drug families and for various combinations of drugs,
  -- Conduct independent tests of these algorithms,
  -- Test subjects with various combinations of drugs and alcohol,
  -- Produce and test equipment that can be used in the field.

- If these can be done, the ENG technology as used in the Veritas™ appears to be a method that could be used for detecting drug and alcohol use. Actual use will require additional development and testing, including:

- -- Develop a training program for Veritas™ users,
- -- Conduct a full field test with a variety of potential users (police, hospitals, drug clinics),
- -- Assess and counter evasive strategies of uncooperative subjects,
- -- Admit Veritas™ findings as evidence in court.

- o Were Veritas™ to work as designed, it could identify the presence of various drugs in an individual. The police would use this information to do further testing (e.g., blood samples analyzed at a laboratory). Veritas™ would not provide evidence on the impairing effects of drugs on the driving task. It would merely provide evidence of drug use.

In summary, corneal retinal potential technology, as incorporated into the Veritas™ device, is a pioneering effort in drug detection. Both the technology and the Veritas™ are still being developed. There are still substantial problems to be resolved, but the evidence at this stage suggests that there is a reasonable chance that Veritas™ can be developed to perform as an indicator of drug use. Its usefulness as a dosage-level and impairment-measurement device depends on completing the Veritas™ development successfully and on further progress in understanding the role of drugs in traffic safety. Should Veritas™ pass the many hurdles ahead, it could be a useful tool for traffic law enforcement.

Table of Contents

	Page
Executive Summary	i
Introduction	1
Organization of Report	1
Technical Background	1
Research Review	3
Research Quality	3
Drug "Signatures"	4
Diagnoses Using Drug Signatures	5
Commercial Developments	8
Veritas™ 100 Analyzer	9
Algorithm Development	10
Computerizing Expert Diagnostic Skills	11
Algorithm Tests	11
Discussion	13
Additional Issues	14
Conclusions	17
References	19
Exhibit: Veritas™ 100 Analyzer	20

List of Tables

Table 1. Diagnostic Accuracy for Two Human Experts Combined..... 7

Table 2. Summary of Experts' Diagnoses of Various Drugs Made in Early Stages of the Research 8

Table 3. Human Experts Vs. Alcohol Algorithm 12

Table 4. Experts Vs. Alcohol Algorithm Using Univ. Pennsylvania Data 13

Table 5. Algorithm and Expert Performance Across Multiple Studies 15

POTENTIAL FOR APPLICATION OF CORNEAL RETINAL POTENTIAL MEASUREMENTS TO DETECT ALCOHOL AND DRUG USE

INTRODUCTION

In Section 203 of Public Law 100-17 of the Highway Safety Act of 1987, Congress authorized the Secretary of Transportation to

> "...test a new drug and alcohol testing technology which measures corneal retinal potential as exhibited in the brain function wave form...to determine the potential for applying such technology and devices in preventing drug and alcohol related traffic deaths."

This new technology resides in a single commercial device which the National Highway Traffic Safety Administration (NHTSA) arranged to test in response to Congress's request. However, the device continues to undergo development and a lapse in its scheduling prevented any testing by the government in time for this report. Consequently, NHTSA's examination is based upon a review of existing data and information provided by the developers rather than on an active test of the technology itself.

Organization of Report

Following the Introduction, the report continues with a Technical Background section providing the reader with the minimum technical information needed to understand the electronystagmograph (ENG) technology. Next is a Research Review of the technical papers of the ENG researchers, which provide the basic data addressing the validity of this technology. This is followed by a section on Commercial Developments which have led to the production of a automated system designed to reproduce the judgments of human experts. A Discussion section looks at the available evidence regarding three key questions on the validity of the technology. Finally, Conclusions are presented.

TECHNICAL BACKGROUND

The term "corneal retinal potential" (CRP) refers to an electrical difference ("potential") existing between the cornea and the retina of the eye. This potential creates an electrical field in front of the face that changes as the eyeballs rotate. Medical research has determined that this potential is affected by the functioning of the body's stability and coordination system made up of the eyes, the brain, and the skeletal muscles that maintain a person in an upright position. This can also be called the body's balance system. While a part of the balance system, the eyes also play an additional role by reflecting how well the system is operating. The corneal retinal potential produced by eye movements can be measured and recorded with a

machine called an electronystagmograph (ENG). Measurement of corneal retinal potential has a long history in the diagnosis of various balance disorders. The ENG has been used for decades by otolaryngologists (medical specialists concerned with the ear, nose, and throat) as a standard diagnostic tool for such disorders as vertigo, Meniere's syndrome, inflammation of the vestibular apparatus, and other abnormalities that influence the balancing mechanism.

In recent years, interest in the ENG test went beyond its conventional use to a quite different application -- that of identifying persons who are under the influence of alcohol and drugs. But what do drugs and alcohol have to do with a test previously used to detect physical illness? The answer is that drugs and alcohol affect man's balance system, and measurements of this system's performance -- through the ENG and corneal retinal potentials -- may reveal drug effects at work.

Balance tests have long been used to detect alcohol intoxication. Research sponsored by NHTSA (Burns and Moskowitz, 1977, Tharp, Burns, & Moskowitz, 1981) produced a battery of sobriety tests for use at roadside by law enforcement officers. Two of the three tests (One-Leg Stand, and Walk and Turn) directly involve balance while the third--Gaze Nystagmus--refers to a particular kind of eye movement. (The "One-Leg Stand" and the "Walk and Turn" tests, more significantly, also involve a test of the ability to divide one's attention between two or more things, a skill critical to driving.) Thus, the concept that balance and eye movements are reflective of at least one kind of intoxication -- alcohol intoxication -- is accepted in the traffic safety area.

The balance system does not operate in isolation. Many areas of the brain presumably have connections to it and to the nerves which influence eye movements. And it is known that specific areas of the brain tend to be affected by families of drugs, such as opiates or hallucinogens. Taken together, these facts suggest the possibility that various drugs which affect the brain will reveal their presence through abnormal corneal retinal potentials.

The new application of the ENG came about because of two factors. One was a heightened interest in drug-detection methods, while the other was the long-standing requirement of the ENG test that a patient be free of drugs because drugs affected the test results. Drugs, in this context, were an annoyance which confounded the physician's findings. That is, they would add their own bit of noise to the electrical signals recorded by the ENG. But, with drugs taking on increased importance as a health problem in our society, attention turned to an intriguing question: could the ENG test with its sensitivity to drugs be used to make reliable identifications of various drugs?

This question was of particular interest to Dr. S. Thomas Westerman, MD, an otolaryngologist, and to his colleague, Liane Gilbert, who have been the principal researchers in this area. In 1980, Dr. Westerman was stimulated by the inquiry of a patient who was also a policeman. Having been made aware of the ENG's sensitivity to drugs, the patient asked if it could be used to identify drugs. This question started Westerman and Gilbert on research that continues to the present time.

RESEARCH REVIEW

In a series of four research articles published over a span of 6 years and covering research begun in 1980, Westerman, Gilbert and colleagues explored the field of ENG waveforms as they are influenced by a wide variety of drugs including alcohol. The evidence reviewed by NHTSA consisted of these journal articles, supplemented in some instances by computer printouts of supporting test data, and information provided by the researchers in response to NHTSA's questions. Background information was also obtained from a Veritas™ Training Manual and a Prosecutor's Guide (both draft versions). NHTSA staff personnel also visited the offices of National Patent Analytical Systems, Inc., the development corporation for the Veritas™ device, and conferred for two days with the research staff, who were most cooperative.

Research Quality -- It should be noted that the research articles, which form the primary materials for this review, generally fell short of standard procedures for reporting research. Detailed information was often lacking on how the diagnostic process was accomplished by the human experts, i.e., what records were looked at under what conditions, what information did the experts have as background. For example, did they know the number of drugs under consideration in the records being analyzed or was the diagnostic task totally open-ended? Were double-blind procedures used? Data presentations and details on how the diagnostic process was scored were also lacking; this would hinder a reader who attempted to conduct a corroborating analysis. Often, the results were so dramatic -- 100 percent correct diagnoses -- that supporting data could be imagined, but the general standard that sufficient description and data be presented to allow the reader to replicate the procedure and to check on the analyses was not always met. "Gaps" in these areas were frequently resolved only by contacting the authors directly. The technical shortcomings of the reported research create an unfortunate barrier to reviewing the ENG technology.

The research shows improvement over time. The early work was a search for data to test the viability of the drug signature concept. Eventually, a large pool (2,000 or more cases) was compiled, but it is uncertain when reading the journal articles whether repeated use was being made of some of the cases, or whether new cases are being reported on. Over time, the research improved, moving away from use of accidental samples (surgical candidates and patients) to more purposive data-collection efforts, and displaying greater adhere'adherence to double-blind procedures and written test protocols. The latest test plans call for work by independent researchers at several locations using different types of subjects.

The research review centered on three questions which underlie the new technology:

1) Do drugs and alcohol present a characteristic "signature" in the ENG waveforms?

2) Can human experts read these signatures and make reliable and valid diagnoses based on them?

3) Can this diagnostic process be computerized to permit widespread application of the technology?

1. Do drugs and alcohol present characteristic "signatures" in the ENG waveform?

Drug Evoked Potentials -- In 1981, Westerman and Gilbert first introduced the idea of using the ENG waveform as a noninvasive method for identifying drug intake. Their review of the literature concluded that while the value of the ENG for assessing impairment effects due to alcohol was becoming more well known, "...its use with other drug intake for qualitative diagnostic purposes has not yet been appreciated by the scientific community."

The purpose of their study was to see if a specific printout or signature could be obtained with certain drugs while subjects underwent the ENG test. Using a battery of eight tests which stimulated the subject's balancing system, ENG waveforms were recorded. The drugs and the number of subjects used included: alcohol (n=54), diazepam (n=19), ketamine (similar chemically to PCP - Angel Dust, n=16), opiates (methadone hydrochloride n=5, and Sublimase n=22), barbiturates (sodimum pentathol n=16), and cocaine (n=10).

The ENG waveform records of the subjects were then examined by the authors to determine if the drugs produced a pattern or an effect that was specific to the drug administered. Pattern analysis is a subjective process at which humans excel. They found that they were able to distinguish among the various drug records by assessing the frequency, amplitude and character of the ENG printout.

Going further, they hypothesized that "...differences in printouts might be the result of each drug affecting different parts of the brain, which influences the balancing mechanism." Suggested applications for this non-invasive technique included: evaluation by emergency room personnel to determine drug identity in overdose cases; allowing obstetricians to monitor a mother suspected of taking illegal drugs, to aid in the treatment of her and her child; and monitoring the effects of anesthesia in the operating room.

There are difficulties with this research, principally in the selection of subjects and conditions associated with them. Some of the subjects were already on prescription for a drug; this introduces two factors which may confound the research. One is the issue of long-term versus short-term drug usage along with adaptation effects, while the second is the presumed presence of some medical condition which required the drug. The paper also notes that 54 of the subjects (patients) were anesthetized, presumably during the testing itself. It is possible that any of these conditions might affect the production of a "typical" waveform for the drug or drugs in question. This research, therefore, must be considered exploratory due to the presence of several potentially-interfering factors. Finally, no details are provided on the process used to identify patterns among the drug waveforms.

2. Can human experts read these signatures and make reliable and valid diagnoses based on them?

Drug Diagnoses -- Westerman and his colleagues continued their research, and in 1984 a second paper was published. It reported on: new waveforms from other drugs (tranquilizers, caffeine, aminophylline, dopamine), extension of the technique to new classes of subjects (newborns and their mothers, surgical candidates), and on waveforms resulting from 75 combinations of drugs. (The issue of detecting combinations of drugs is a complex one. There is some evidence that one of the experts, Dr. Westerman, may be able to diagnose some drug combinations from the ENG waveforms. However, the question of whether this skill could be computerized remains unanswered at this time. The issue is complex due to the fact that while some drugs may retain their individual signatures when combined, other combinations may be highly interactive with two drugs combining to form a modified or new signature characteristic of neither drug.) Having established to their satisfaction that drug specific waveforms, termed drug evoked potentials (DEP), could be identified using the ENG, the researchers took the next step, that of testing themselves to see how accurately they could identify drug effects based on waveform analysis.

Double-blind procedures were used where neither the ENG technician nor the diagnosing physician knew which drug was being administered at the time of testing. The waveforms obtained were analyzed by comparison with waveforms obtained in previous research. Waveforms from new drugs (for which no characteristic printout yet existed) were determined in this study by "... first analyzing the first five results, and when consistencies were noted, using the other 29 tests as materials for double-blind studies."

All of the identification tests were reported by the authors to be highly successful. No false positive or false negative identifications (errors) were made for any of the drugs tested. Further, drugs belonging to the same family were found to produce identical waveforms. For example, sodium seconal ans sodium pentathol produced identical waveforms as did morphine sulfate and fentanyl. It was also determined that repeated administration of a drug (phenobarbital using neonates, and dextroamphetamine using adults) produced identifiable waveforms which were repeated consecutively with each test. That is, these drugs, when given to the same people over several administrations, produced the same waveforms. Thus, the drug evoked potentials demonstrated the quality of reproducibility within individuals.

Better experimental conditions were maintained for this study. Double-blind procedures were used along with placebo conditions. Drug subjects did not have a history of being on the drug under test. Baseline testing, followed by drug testing, permitted before-after comparisons. Surgical candidates, anesthetized, and with existing medical conditions requiring surgery, were still used as subjects, however. It is also noted that this article provided no quantitative data, i.e., tables, charts, tests of significance, etc., to support the authors' findings, or to allow the reader to form his own conclusions. (Data are provided in later papers, however, which speak to this point.)

Critique: In a discussion section appended to the 1984 paper, a reviewing physician (an otolaryngologist) commented on it, noting the lack of technical information relevant to the testing situation itself (characteristics of the amplifier, impedance values between skin and electrodes, etc.). Regarding the characteristic waveforms for the various drugs, he stated he was "...struck by the fact that a number of the records published [in Westerman and Gilbert's 1981 paper] showed qualities that appear in normal individuals under varying conditions of mental alerting with eyes closed.." Finally, the reviewer commented on the authors' report of no false positive or false negative identifications in any of their trials: "Strip records of biological function are rarely if ever so distinctive, so decisive and clear that this remarkable confidence in their interpretation can be relied upon." The reviewer felt that, until another study was conducted, preferably in two or more places with strict experimental control, these findings should be "...accepted with extreme caution."

In a 1986 paper presented at the 10th International Conference on Alcohol, Drugs and Traffic Safety in Amsterdam, Westerman, Gilbert, and Willier provided additional evidence on the two experts' diagnostic abilities using ENG waveforms. A total of 245 subjects were used in acquiring ENG waveforms under baseline and normal conditions and a number of drug conditions: alcohol, cocaine, morphine, and marijuana. In what appears to be its first use, the Veritas™ 100 Analyzer was the data collection instrument. The 245 subjects were used to generate 392 drug waveforms (certain subjects were tested on more than one drug). The two experts analyzed the waveforms in groups of 20 to 40 sets selected at random. Though the published paper presents only summary statements about the results, additional data were requested from and provided by the authors to NHTSA for its own analysis. The results of this analysis are shown in Table 1.

The two experts each made 392 diagnoses of the waveforms produced by the 245 subjects, some of whom appear in more than one drug group. In determining the accuracy of the diagnoses, the five "unknown" decisions are excluded from the set, leaving 779 decisions. Using 779 as the base number, the decisional outcomes were as follows:

True Positive (correct) Decisions = 750/779 = 96.3%

False Positive (incorrect) Decisions = 2/779 = 0.25%

False Negative (incorrect) Decisions = 27/779 = 3.5%

The human experts were highly accurate in their diagnoses, identifying the given drug family correctly 96.3 percent of the time. The error pattern is also relatively benign, with the more costly error type--false positives which involve saying a drug was present when it was not--occurring in less than one percent of the diagnoses. The false negative decisions, while more frequent, are also somewhat acceptable in that they do not falsely place a person in jeopardy.

TABLE 1. Diagnostic Accuracy for Two Human Experts (Westerman and Gilbert) combined.

	Experts' Diagnoses (2 Experts @ 392 Cases = 784 Diagnoses)					
Drug Groups (N)	Normal	Alcohol	Marijuana	Cocaine	Opiate	Unknown
None (221)*	439	1	1			1
Alcohol (40)	10	68				2
Marijuana (39)	9		67			2
Cocaine (55)	8			102		
Opiate (37)					74	

*This group consists of baselines taken of the drug group subjects before drugs were administered plus controls who did not get drugs.

Pathology Versus Drugs --In this same 1986 paper, Gilbert, Westerman, and Willier reported testing patients with otolaryngolocal complaints, patients who had suffered head trauma, and geriatric patients in a nursing home. The purpose was to determine if pathological conditions could be mistaken for drug evoked potentials. The authors reported: "None of the pathologies examined in this preliminary study produced a waveform that was compatible with the drug evoked potentials identified." No data, however, are provided in the article to support this statement.

The authors noted studies which suggest that the reticular activating system--responsible for the regulation of sleep and wakefulness, and for the coordination of gaze and eye tracking movements--plays a role in the creation of drug evoked potentials. They concluded that there is evidence strongly supporting the idea "...that psychotropic drugs either directly or indirectly affect the region of the brain that influences the production of the waveform obtained by a standard electronystagmograph."

A Need For A New Device -- Given the wide range of applications foreseen by the developers, the need was recognized as early as 1983 to widen the use of this technology by automating the process. In its broadest sense, this would entail packaging the standard test situation, an ENG machine, and the diagnostic process into a single unit that a variety of users (law enforcement officers, hospitals, clinics, etc.) could employ. The most difficult part would be to incorporate the diagnostic skills of the human experts into a computer program.

At this point, before addressing the third question, -- whether the human experts' diagnostic skills can be computerized -- it will be helpful to describe briefly the corporate or commercial activities which form an important part of the automation phase.

COMMERCIAL DEVELOPMENTS

In 1983, Westerman and Gilbert met with National Patent Development Corporation (NPDC) to seek commercial support for the development and marketing of an automated system for screening for drugs. In support of their claims, they provided a summarization of their ability to diagnose a variety of drug subjects (see Table 2.). It is important to realize that these data represent a cumulative record of the early developmental activities, and they are not, according to the researchers, of pure research quality. For example, no strict protocols or fixed experimental procedures were followed. Subjects in these early days (mainly surgical candidates and in-house patients) were acquired as the opportunity presented itself. Some of the tests were not conducted under double-blind conditions, i.e., the researchers would know beforehand what the drug was. Despite these limitations, the data present a strong picture of the experts' diagnostic skills when using ENG waveforms to identify drug effects.

A subsidiary of NPDC, Pharmometrics Corporation, took on the task of developing and marketing an automated ENG analysis system for detecting and identifying drugs. Toward this goal, Pharmometrics produced the ADMIT System. (No description will be provided as the ADMIT system was replaced by the Veritas™ system to be described later.) They also began development of a critical part of the system, namely, software encompassing a procedure or "algorithm" for analyzing the ENG waveform in the manner used by the human experts.

TABLE 2. Summary of Experts' Diagnoses of Various Drugs Made In The Early Stages of the Research

Number of Double-Blind Cases	Drug Classification	Correct Diagnoses*	False Positive	False Negative
22	Hallucinogens	22	0	0
13	Tranquilizers	17	0	1
126	Opiates	141	0	8
42	Barbiturates	46	1	0
37	Cocaine	39	0	0
61	Alcohol	76	0	6
12	Marijuana	18	0	0
31	Amphetamines	34	0	0
9	Xanthines	9	0	0
52	Placebos	52	0	0
128	Controls	125	3	0
533		579	4	15

*Not all of the cases diagnosed were under double-blind conditions; therefore, the totals for the three decision outcome columns on the right may exceed the number of double-blind cases for that drug category.

This first attempt at algorithm development used a statistical approach to mimic the performance of the experts; it proved unsuccessful. (In that same period, a test of the general qualities of the ADMIT System at Johns Hopkins Medical Center ran into problems when it was found that the unit had an electrical leakage problem. This was later resolved and testing was resumed, but no data are available from this test effort.)

In July of 1985, responsibility for the system switched from Pharmometrics to Analytical Systems, Inc., another subsidiary of NPDC. Under their direction, the ADMIT System evolved into the Veritas™ 100 Analyzer (see Exhibit 1.). After exploring additional statistical approaches to algorithm development, "knowledge engineering", a new branch of computer science, was applied to developing the drug algorithms. An alcohol algorithm was developed which had some success and work began on the second target, a cocaine algorithm. Plans were made to broaden the experimental data base to include work by other laboratories and investigators, but these plans, and others involving a field test in conjunction with NHTSA, fell behind schedule when hardware for the field was not developed on time. At last report, the parent company's plans regarding Veritas™ were still being formulated.

This review of the commercial developments indicates that there has been a progressive improvement as these companies made their contributions to improving the CRP technology. The pattern, as observed by NHTSA, has been an increase in awareness of what is needed to produce a valid system.

The next sections will discuss the Veritas™ 100 Analyzer, the algorithm development efforts, and additional research by Westerman and colleagues.

Veritas™ 100 Analyzer

The Veritas™ 100 Analyzer is a computerized data collection and analysis system designed to be used in fixed locations, e.g., hospitals, police stations, drug clinics, etc. As indicated earlier, the Veritas™ 100 Analyzer derived from the ADMIT System. A product description page is presented as Exhibit 1. The intent was to have Veritas™ collect, store, and analyze waveforms within a five-minute period. A test session would be conducted as follows. The instrument is placed 18 inches in front of the seated subject, with the screen located at eye level. An electrode headband is fitted to the subject. The subject is first presented with two lights placed 6 1/4-inches apart that flash at 1.1-second alternate intervals on the screen for 12.63-seconds. This permits measurement of the subject's electrical potential for standardization of signals. The subject's task during the test session is to remain in the required position (seated or supine; head to the right, left, or straight; eyes open or closed) as directed by the tester.

Runs are then recorded for 34 seconds in each of the following positions:

- Looking at a target on the screen directly in front of the eyes.
- In the same position with eyes closed.

- Facing a target point on the left side of the screen and averting the eyes 30 degrees to a targeted point on the right side of the instrument.

- In the same position with eyes closed.

- Facing a targeted point on the right side of the screen and averting the eyes 30 degrees to a targeted point on the left side of the instrument.

- In the same position with eyes closed.

- Lying supine with the head turned to the right so that the ear was flat to the chair, with eyes closed.

- Lying supine with the head turned to the left so that the ear was flat to the chair, with eyes closed.

Obviously, this procedure calls for the complete cooperation of the subject, a point discussed later in the report.

Algorithm Development

As mentioned briefly earlier, in the first approach (during the ADMIT System era) taken to developing algorithms to duplicate the experts' diagnostic performance, classical statistical tools were applied. The algorithm development phase of this work involved approximately forty-hours of dialogue between the developers and the experts. While initial results looked promising, two shortcomings eventually led to the abandonment of this approach. One was the weak correlation between the decisions of the algorithm and the experts, while the second was that the algorithm's diagnostic ability declined when exposed to totally new ENG records.

When the statistical approaches to algorithm development proved unsuccessful, a different approach called "knowledge engineering" was tried. The technical field of knowledge engineering has as its objective the creation of computerized "expert systems" or an artificial intelligence designed to capture the reasoning process used by experts in a particular field of endeavor. It is an esoteric area, blending psychological theories about human perception and cognition with computer languages and models. To quote from a description of the process:

> "The Gilbert and Wilson algorithm was developed with the goal of recreating the DEP identification approach used by the human experts. To do so, this work ultimately ended up merging visual perception theory with expert system technology. The algorithm can best be described as the interaction of three modules. The first is the Atomic Description Module which describes the waveform as a set of very simple movements such as line and curve segments. Next is the Perception Module which takes these simple movements and combines them according to proximity and similarity operations so that consistent and sustained movements are grouped together. Last

is the Cognition Module which utilizes the information generated in the Perception Module to generate and verify hypotheses. The development phase of this work has, to date, required several thousand hours of discussion with the human experts. The correlation of the algorithm with the expert is very good. Also, since the algorithm was not trained on a specific set of data, its diagnostic rate remains constant as it is exposed to new data." (Source: Personal correspondence from Scott Wilson, Knowledge Engineer, NPAS, Inc., 11/2/87)

With this background, the final question on developing an expert system can be examined.

3. Can the human experts' diagnostic skills be computerized to permit widespread application of the technology?

Algorithm Tests

Once the alcohol algorithm had been developed, various tests were made to determine how well it replicated the judgments of the human experts. Each of the tests is described below. (This information was made available in a briefing handout provided by National Patent Analytical Systems, Inc., staff personnel, 4/20/87.)

On Alcohol Waveforms -- Waveforms of 41 subjects with a range of blood alcohol concentration (BAC) levels were analyzed by both the human experts and the alcohol algorithm. RESULTS: Table 3 presents the data for this substudy. The experts were correct in 90 percent of their diagnoses as to the presence of alcohol, and the algorithm matched the experts' diagnoses 81 percent of the time. Note also the general tendency for the diagnoses of both the experts and the algorithm to become more accurate as the BAC or dose level increases. On the baselines (no alcohol) made for this same group (data not shown), both the algorithm and the experts diagnosed 100 percent of the cases as negative for alcohol.

False Positive Diagnoses -- False positive diagnoses are errors in which a drug is diagnosed to be present when it is not. To test for this feature, 396 trials obtained from drug-free, alcohol-free subjects were analyzed by both experts and the program. RESULTS: 100 percent of the non-alcohol (and non-drug) cases were correctly diagnosed by the experts as being negative for alcohol, and the algorithm correctly diagnosed 98 percent of these trials.

Other Drugs -- This study examined the question of whether the alcohol algorithm would mistake a drug record for an alcohol record. Waveforms of 60 subjects were analyzed by the alcohol algorithm. These subjects had been administered one of the following drugs : marijuana, cocaine, dextroamphetamine, sodium seconal, diazepam, or morphine sulfate. RESULTS: 100 percent of the tests performed on subjects taking a drug other than alcohol were diagnosed as negative for alcohol by both the experts and the algorithm.

TABLE 3. Human Experts Vs. Alcohol Algorithm (N = 41 Cases)

Percent Correct Predictions of Alcohol Presence

BAC Range	Number of Cases	Hum. Experts True Positive Freq.	Hum. Experts True Positive %	Algorithm True Positive Freq.	Algorithm True Positive %
Unknown*	7	6	86	4	57
Greater than .00 but less than .05	2	2	100	1	50
Greater than .05 but less than .10	16	14	88	11	69
Equal to or greater than .10	16	15	94	14	88

*Not able to measure BAC, but alcohol was present

Independent Study -- In a small substudy conducted independently at the Medical College of Pennsylvania, six subjects were tested at baseline (zero BAC), brought to BAC levels of 0.10% or higher, and then tested using the Veritas™ 100 Analyzer at intervals of 30, 90, 150, 180, and 210 minutes. Alcohol breath tests were also administered. The waveforms were then sent to the experts for their diagnoses and those of the alcohol algorithm. Table 4 presents the results of these analyses.

These results indicate that the diagnostic skills of both the human experts and the algorithm vary systematically with the alcohol dosage level. That is, both are perfect in detecting non-alcohol conditions, both have difficulty with low (greater than .00% but less .05%) BAC levels, both improve as the dose increases, and finally, both reach a BAC level (equal to or greater than .10%) where the diagnosis is absolute.

These results indicate that the alcohol algorithm appears capable of duplicating human experts' judgments regarding the presence or absence of alcohol from analysis of ENG waveforms. In a 1987 article, Westerman and Gilbert provide an overview of their research over the years, concluding with the work done on the alcohol algorithm.

TABLE 4. Experts vs. Alcohol Algorithm
Using Univ. Pennsylvania Data

Percent Correct Predictions of Alcohol Presence

BAC Range	Number of Cases*	Hum. Experts True Positive Freq.	Hum. Experts True Positive %	Algorithm True Positive Freq.	Algorithm True Positive %
.00	6	6	100	6	100
Greater than .00 but less than .05	10	3	30	1	10
Greater than .05 but less than .10	13	7	54	3	23
Equal to or greater than .10	7	7	100	7	100

* 6 Subjects with 6 measurements each = 36 cases

DISCUSSION

This section reviews the evidence regarding the three questions posed in the beginning of the report.

1. Do drugs and alcohol present characteristic "signatures" in the ENG waveforms?

This question is at the center of the research. If signatures do not exist, then all that does exist is a new device for measuring ENG waveforms. However, it is not possible to answer this question directly within the time constraints of this report. The drug evoked potentials (DEPs) or characteristic signatures are said to consist of relatively subtle and complex differences in the ENG waveforms which tend to be similar for families of drugs. It is difficult to judge their existence by looking at the waveforms themselves. For example, Dr. Westerman estimates that months of training -- equal to that needed to read EKG records -- are needed to learn to read the waveforms. With only two people trained to read them now (these being the originators of the technique), it is unlikely that their existence will be proved or disproved by debate alone. A more indirect form of proof lies in their usefulness. What levels of diagnostic accuracy and error are achieved using the DEP approach? This leads to the second question.

2. Can human experts read these signatures and make reliable and valid diagnoses based on them?

Based on the evidence reviewed to date, it would appear that they can. In

the two major presentations of the experts' diagnostic abilities (see Tables 1 and 2), the results show a true positive rate in the high 90 percent range, with relatively few (less than one percent) critical errors being made. A fairly extensive range of drugs is correctly identified in these data sets. To make judgments as accurately as this indicates that the experts are relying on some kind of predictive information which, unless deception or significant procedural errors were to be involved, points strongly to the concept of DEPs. Therefore, to the extent that the human experts are very successful in identifying drugs based on ENG waveform analysis, credence must be given to the concept of drug evoked potentials as the basis for this diagnostic skill. Additional support would also be demonstrated if this DEP-based diagnostic skill could be imparted to a computer.

3. Can this diagnostic process be computerized to permit widespread application of the technology?

The researchers chose alcohol as the first drug for which an algorithm was developed. Although better technologies exist for measuring blood alcohol content, i.e., breath testers, it is appropriate for the Veritas™ device to have this capability. This is because an impaired driver sometimes tests negative for alcohol, in which case the next question is "are drugs involved?". Thus, there is a need for measurement capability in both areas. When the researchers deal with alcohol, the issue of dose level is highlighted. That is, the emergence of definitive DEP patterns may be dependent on the amount of the substance consumed by the subject. This appears to be the case with alcohol, and the researchers suggest that other drugs may follow this course. This, of course, brings in the time variable which will also act to vary the substance amount. These are, as noted by the researchers, two critical interrelated areas of future research. For present purposes, we note only that diagnostic accuracy for both the human experts and the algorithm improves dramatically as higher BAC levels are reached.

Does the alcohol algorithm based on knowledge engineering techniques work? Again, based on the evidence available, the answer appears to be yes. As Table 5 shows, there is near perfect agreement between experts and algorithm in recognizing "alcohol-free" waveforms; both operate at or close to 100 percent correct identification. Similarly, the experts and the algorithm are equally perfect in not confusing other drug waveforms as alcohol. Moving on to the two alcohol data sets referred to above (Tables 1 and 2), the experts have correct diagnoses at the 90 percent and 64 percent levels for "in-house" data and the University of Pennsylvania data, respectively. The algorithm mirrors this to a certain extent with 73 percent and 47 percent correct diagnoses for these two data sets. That indicates that the algorithm matches the experts' decisions 81 percent and 73 percent of the time, respectively.

Additional Issues

The research review focused on the origins and supporting research of the ENG technology. In addressing Congress's concern about the potential of this technology, it is also appropriate to look ahead at the work that remains to be done, and at the roles that a Veritas™ device might play. This will serve to identify future requirements and potential stumbling blocks.

TABLE 5. Algorithm and Expert Performance Across Multiple Studies

	ZERO ALCOHOL (n = 396)	OTHER DRUGS (n = 60)	ALC RANGE (n = 41)	UNIV. PA (n = 36)
EXPERT	100	100	90	64
ALGORITHM	98	100	73	47
% AGREEMENT	98	100	81	73

Remaining Work -- Further work for the Veritas™ device that would move it out of the laboratory and into the field includes developing and testing of diagnostic algorithms for drugs other than alcohol, conducting independent research at a variety of user sites, producing field-ready equipment, and providing training and support for users. Progress is being made in each of these areas. A critical area would be the development of algorithms for drug combinations. Multiple-drug use among drug-impaired drivers appears to be a frequent event which Veritas™ will need to address, not only for the sake of thoroughness in detecting all of the drugs active in a person's system, but for accuracy in the case where drug combinations create signatures different from those of the individual drugs being combined.

An Operational Role -- Within the traffic enforcement area, Veritas™, if effective and fully operational, would serve to identify drugs affecting an individual. Testing would presumably be done at a police station. However, the device could function in this way only if a number of conditions exist. For example, either the person being tested volunteers to take the test, or State laws are modified to penalize drivers refusing to take lawfully requested ENG tests. Since it is unlikely that many drivers may subject themselves voluntarily to increased legal risk, use of the device in the traffic enforcement area will probably require its inclusion under State implied consent laws. Present laws requiring license holders to submit to alcohol or drug tests typically specify the nature of such tests, i.e., blood, urine, breath; no provisions presently exist for ENG waveforms. Even with the existence of legal persuasion, the test may require such a high degree of cooperation from a suspect that noncompliance in one form or another may be the rule rather than the exception, i.e., it may not work due to lack of cooperation. This is a major issue to be examined in operational tests made in the field. Before evidence generated by the Veritas™ could be used in a trial, its scientific validity would have to be established and the device shown to be reliable.

Assuming that these legal issues were settled, Veritas™ could be used to identify drugs. The police would use this information to do further testing (e.g., blood samples analyzed at a laboratory). The major contribution made by Veritas™ would be to develop this information more quickly and at less

cost than presently possible. That is, on-site testing would be relatively quick, and the information would allow the police to have the blood-testing laboratory narrow its focus to one or two specific drugs rather than performing general screening tests which then require followup testing.

Will it be possible for Veritas™ to not only identify drugs a suspect has taken for the purpose of justifying blood tests, but become legally acceptable evidence in and of itself? That is, to substitute for laboratory blood or urine tests? Could it serve as the drug counterpart to the breathalyzer machine? The answer is that this is very unlikely, either now or in the immediate future. The reason is that the drug-driving area does not have a knowledge base supporting it that is comparable to the alcohol-driving area. This limits the degree of acceptance likely to be accorded to a drug-identification device such as Veritas™. A qualified breathalyzer measures blood alcohol concentration (BAC) through an accepted conversion formula based on a breath-to-blood ratio. Its BAC readings are legally accepted as evidence in all states. BAC level, in turn, has a known relationship to the risk of having an accident on the highway. Further evidence from extensive laboratory research has shown that various BAC levels induce impairment in driving-related skills. Driving simulator research and on-the-road studies also demonstrate the impairing effects of alcohol. The totality of this convergent body of knowledge has convinced the legislative and judicial systems to accept the relationship of BAC to impaired driving and increased risk of accidents. Per Se (sufficient evidence in and of itself) and presumptive BAC levels have been established and written into law. Testing standards have been set and applied to breath test devices seeking to qualify as evidential units.

Drug identification devices to establish impairment are not yet supported by an equally persuasive body of scientific evidence. Although it is clear that drugs other than alcohol contribute to highway crashes, the relative risk of a crash incurred by using some dose level of a drug or combination of drugs is not yet known. It is also clear that many drugs impair psychological and behavioral abilities that are functionally related to driving. However, there is not a full understanding of the impairing effects of all drugs on skills critical to driving at different usage levels. Many of the drugs in question are illegal. If a state wishes to prosecute for "use" of an illegal drug, a drug-detection device will suffice. But where the charge is not use of an illegal substance, but driving while impaired, more research will be necessary to develop an acceptable detection system. Further, there are no drug-driving laws analogous to the .10 percent BAC per se law.

The technology evident in Veritas™ does not overcome certain common problems facing the traffic safety area when it comes to drugs. Veritas™, for example, does not measure drug-induced impairment in driving skills. It presumably measures disruptions in man's balance system, but we do not know what role "balance" plays in driving a car. ("Balance" in the roadside sobriety tests may draw its value from being part of a divided attention task which, in turn, is seen as a critical driving skill; the tests involving balance and divided attention are also predictive of blood alcohol concentration level.) Thus, we cannot, at our current state of knowledge, point to the aberrations presumably caused by drugs in the ENG waveform and

relate them to impairments of critical significance to the driving task. If we wish to measure impairment as opposed to simple usage, the key is research establishing the linkages which have proved useful in the alcohol-traffic safety area. That is, demonstrating impairment in driving-critical skills as a function of dose level, and epidemological work relating dosage to crash experience.

CONCLUSIONS

There are several limiting factors operating in this review of the evidence on corneal retinal potential technology. These include the single-source nature of the data and the limited journal articles reporting on the research. Another was the inability to conduct a planned field test in which NHTSA would have participated. This meant that additional data from a totally new source did not become available. Finally, the device itself is not fully operational, nor has it been tested in any of the real-world situations for which it was designed. With the limitations identified, what are the positive elements of this new technology? What is the potential for applying this technology to the prevention of drug and alcohol-related traffic deaths? The foundations of the technology appear sound, having been developed over decades in support of medical goals other than drug identification. The waveform records produced by the ENG are the product of an established technology akin to other medical areas involving measurements of the body's electrical fields, e.g., electrocardiograph (EKG), electroencephalographs (EEG) and electromyographs (EMG). The impetus for using the ENG waveform as a drug detector was the fact that drugs tended to interfere with its use for other purposes.

There is indirect evidence that various families of drugs produce unique drug evoked potentials or "signatures" in ENG waveforms. The evidence arises from the fact that trained experts can identify different drugs through these signatures. The drug signature concept gets further confirmation from the limited success achieved with the development of an alcohol algorithm. This would indicate that the "knowledge engineering" approach to algorithm development is a productive one.

The technology is not, nor does it claim to be, an infallible indicator of drug use. At low dose levels, a particular drug may not affect the balance system and, hence, the ENG waveform may not reflect that drug's effect. Similarly, the peak effect of a drug on the balance system may occur at a particular time after ingestion; measurements made after that time may not reflect an effect even though the drug is still in the body. The issue of detecting combinations of drugs, a likely real-world occurrence, brings up a host of complex situations (one drug masking another, synergistic effects) which have yet to be explored beyond noting that human experts can detect some combinations using the ENG waveforms.

It is difficult to foresee whether the Veritas^{TM} analyzer will ultimately prove useful in the field due to the many steps remaining before that point is reached. Algorithms need to be developed and successfully tested for drugs other than alcohol. Identifying combinations of drugs must be addressed. Field-ready equipment must be developed. These developments

would move the device out of the laboratory into field experimentation. Independent corroborating research at clinics, hospitals, and police stations employing suitable experimental procedures is a strong requirement. Field work would bring with it the need for a training program for Veritas™ users (one has been drafted), and a strategy for having Veritas™ data made admissable as evidence in court (a Prosecutor's Manual has also been drafted). The device would need to be used in the normal enforcement-adjudication system to test its ability to meet practical, legal, and operational considerations such as police and legal acceptance, cost of use, and resistance to strategies of uncooperative drivers. These are major steps, costly and time-consuming, which must be balanced against the commercial return envisioned by the developers.

In summary, corneal retinal potential technology, as incorporated into the Veritas™ device, is a pioneering effort in drug detection. Both the technology and the Veritas™ are still being developed. There are still substantial problems to be resolved, but the evidence at this stage suggests that there is a reasonable chance that Veritas™ can be developed to perform as an indicator of drug use. Its usefulness as a dosage-level and impairment-measurement device depends on completing the Veritas™ development successfully and on further progress in understanding the role of drugs in traffic safety. Should Veritas™ pass the many hurdles ahead, it could be a useful tool for traffic law enforcement.

REFERENCES

Burns, Marcie and Moskowitz, H. Psychophysical Tests for DWI Arrest. (DOT HS-5 01242), U.S. Department of Transportation, NHTSA, 1977.

Tharp, V., Burns, Marcie, Moskowitz, H. Development and Field Test of Psychophysical Tests for DWI Arrest. (DOT HS-805 864) U.S. Department of Transportation, NHTSA, 1981.

Westerman, S. T. and Gilbert, Liane M. A Non-Invasive Method of Qualitative and Quantitative Measurement of Drugs. LARYNGOSCOPE, Vol. 91, No. 9, pp. 1536-1547, September 1981.

Westerman, S. T., Golz, A., Komorowski, F. S. and Gilbert, Liane M. Qualitative Measurement of Drugs. LARYNGOSCOPE, Vol. 94, No. 2, February 1984.

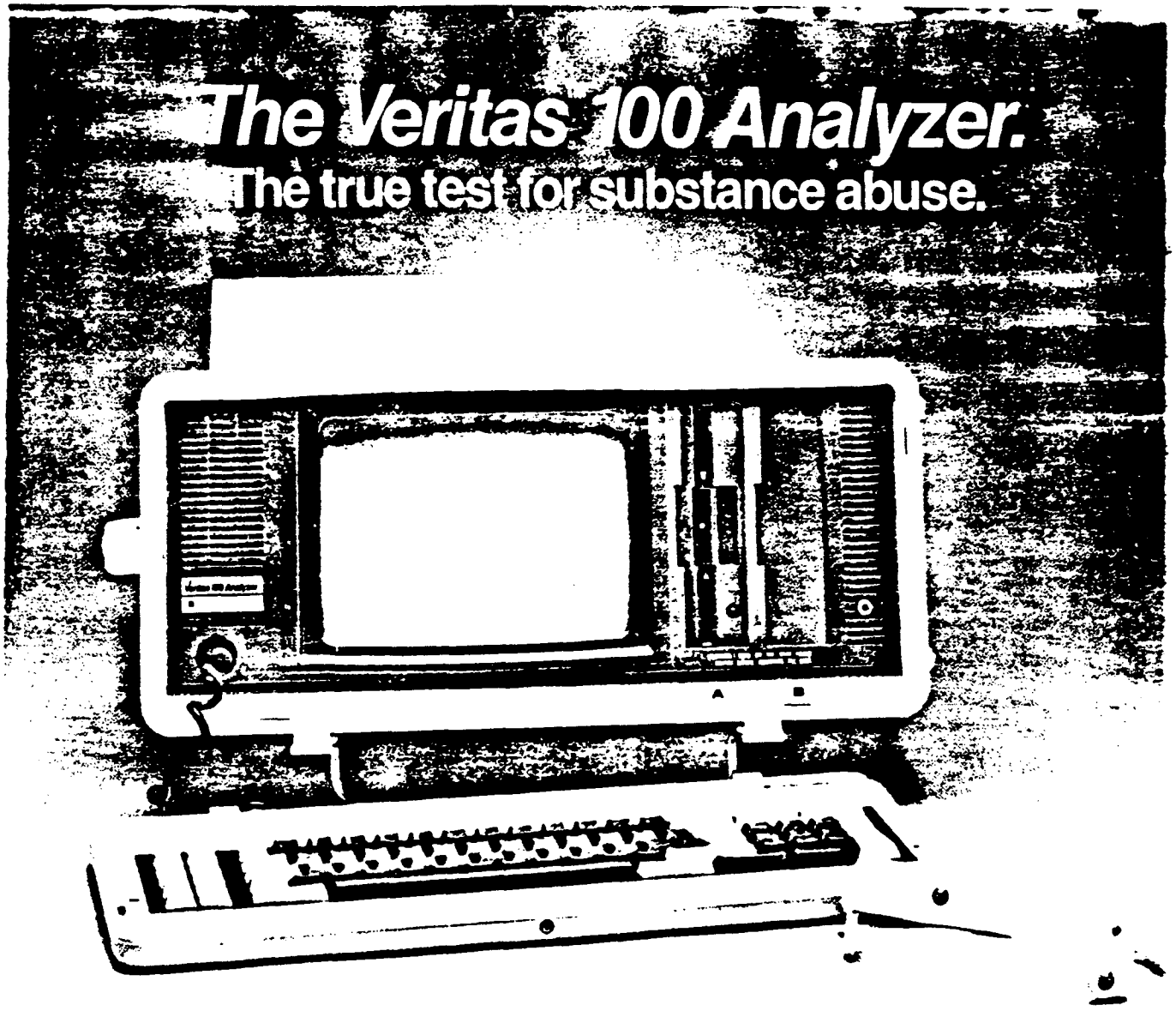
Westerman, S. T., Gilbert, Liane M., and Willier, Jennie. Non-invasive Detection of Psychotropic Drug Ingestion. Paper presented at 10th International Alcohol, Drug, and Traffic Safety Conference (T86), Amsterdam, September 1986.

Westerman, S. T. and Gilbert, Liane M. Advances in Technologies for Alcohol and Drug Testing. Internal Medicine for the Specialist, Vol. 8, No. 6, June 1987.

EXHIBIT

Product Information Sheet:

The Veritas^{TM} 100 Analyzer



The Veritas™ 100 Analyzer: The Drug and Alcohol Detection System

1. Detects the presence of both Drugs *and* Alcohol in *one* test
2. "Fingerprint"-like waveforms for each drug show presence of drugs or alcohol
3. Provides tangible proof of presence of abused substances
4. Eliminates drawing of body fluid samples—one test shows it all

Small Space, Low Cost, High Yield:

1. About the size of a typewriter
2. Unit is transportable, weighing only 35 pounds
3. Immediate results at a fraction of the cost of other testing methods
4. Single operator testing means minimal manpower required

NATIONAL PATENT
ANALYTICAL SYSTEMS, INC.
A SUBSIDIARY OF NATIONAL PATENT DEVELOPMENT CORPORATION

Non-Invasive Method:

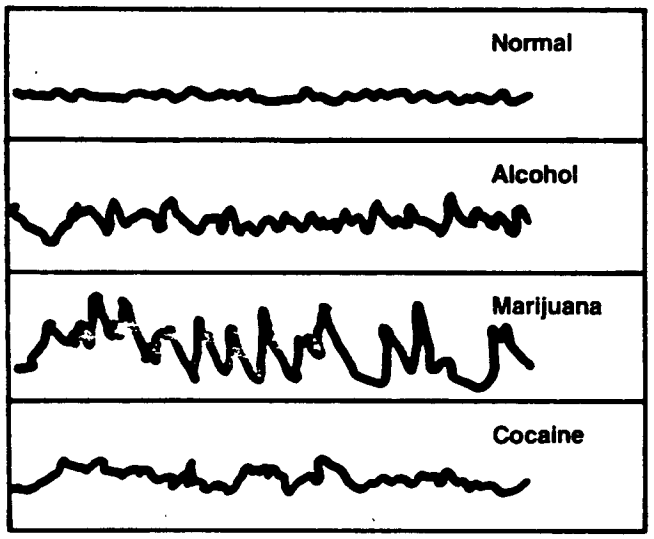
1. No needles or fluids used–reads brain waves for indication
2. Disposable headband insures a reliable test every time
3. Eliminates costly lab fees
4. Minimizes chance of technician error

Fast Accurate Results:

1. Average testing time about five minutes
2. High degree of accuracy
3. Data storage capability maintains all test information and results for future use
4. Data copy feature provides printed readout of conclusions
5. Quick results mean quick decisions

The Veritas™ 100 Analyzer Performs The Work, Minimizing Operator Error:

1. No extensive training needed
2. Automatically compares subject's brain waves with known drug waveforms
3. Determines presence of substance exclusively at the time of testing
4. Complete training and service support from National Patent Analytical Systems



This is a revolutionary method of drug and alcohol detection. Now you no longer have to rely on fluids from every subject when the Veritas™ 100 Analyzer can simply, non-invasively collect a sample brain wave through an easy-to-use, disposable headband.

Years of scientific research prove that drugs and alcohol leave a characteristic "fingerprint" on brain waves. The Veritas™ 100 Analyzer is capable of identifying these characteristics by means of an expert computer system developed to assure the highest statistical reliability.

At National Patent Analytical Systems, Inc. we realize that ours is an ever-changing society where new drugs and substances of abuse become available and used. We plan to continually upgrade our system to keep the Veritas™ 100 Analyzer a product ready to service today's needs.

NATIONAL PATENT
ANALYTICAL SYSTEMS, INC.
A SUBSIDIARY OF NATIONAL PATENT DEVELOPMENT CORPORATION
EXPRESSWAY PLAZA TWO, ROSLYN HEIGHTS, NY 11577 (516)484-3090

*Data on File

☆ U.S. GOVERNMENT PRINTING OFFICE 1988--516-018/80412 Region #3