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Blast Overpressure Studies

By

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May 1998

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To satisfy the Army's need for realistic safe limits for heavy weapons noise while wearing hearing protection, a 2-1/2 year study was undertaken. Using active duty military volunteers, 64 subjects established that the auditory system could be adequately protected with the RACAL muff from one to three exposures of the reverberant waveforms obtained from a rocket launcher out of an enclosure. Thus, nonauditory considerations set the exposure limits for this type of waveform. This research was accomplished under Task Order 1. Using 27 subjects, two types of nonlinear (increasing attenuation with level) hearing protection were evaluated using 6 to 100 exposures of a freefield waveform of 1.5-ms duration. With the limited number of subjects, neither plug was adequate to protect the auditory system from this type of waveform. Several subjects had a temporary threshold shift (TTS) of their hearing of more than 25 dB. The compressible foam plug did appear to provide adequate protection up to the auditory limits for this waveform. This research was accomplished under Task Order 4.

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Daniel L Johnson 27 Aug 96

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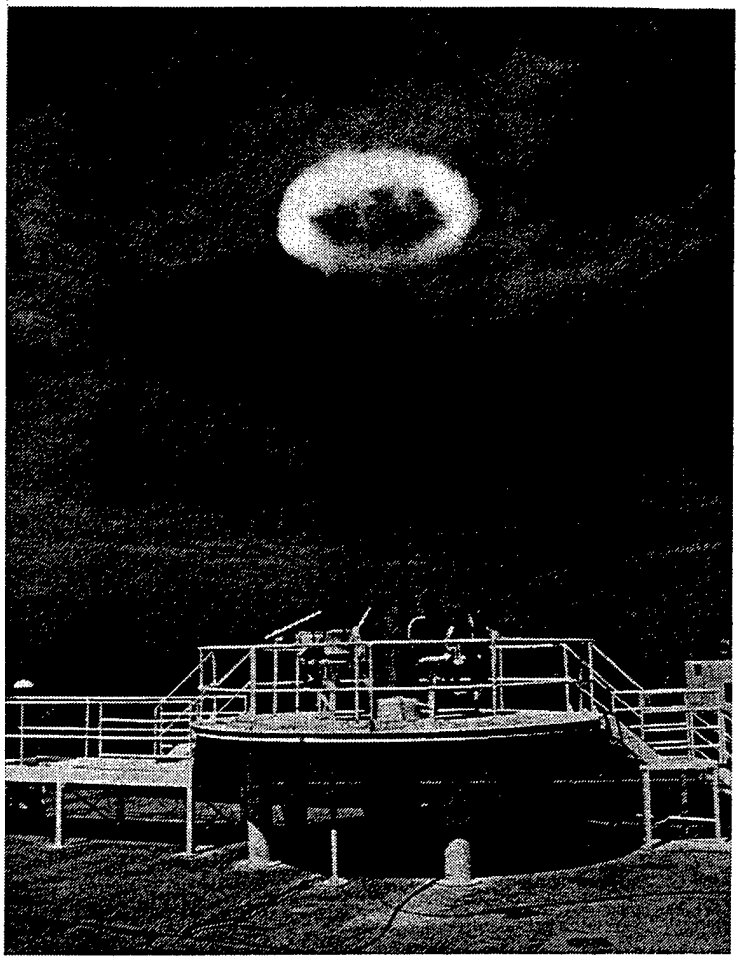
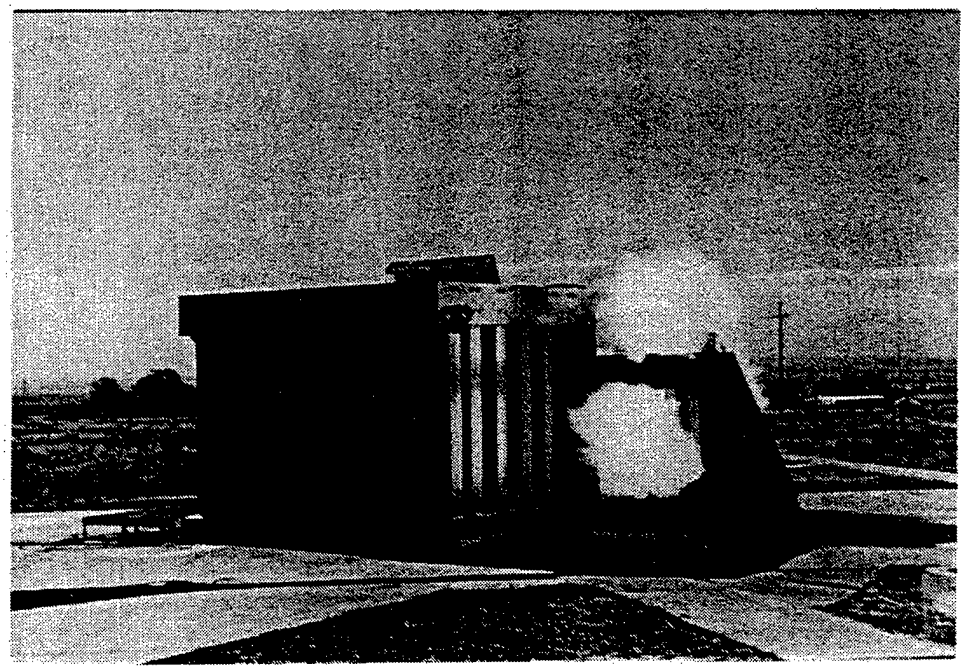


Typical Exposure of Army Volunteers Using the Mortar Simulator Nonlinear Plug Study (Freefield)



Firing from a Bunker Simulator

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I. INTRODUCTION

The objective of this study was to determine the safe limits of occupational exposure, while wearing hearing protection, to impulse noise of both reverberant and freefield waveforms. For the freefield waveforms, characteristic of mortars and howitzers fired in the open, special emphasis was placed on using special nonlinear ear plugs as hearing protection. The nonlinear plugs were designed to produce a minimum speech interference and to provide increasing attenuation as the peak of the impulse increased. For the reverberant waveform, a test apparatus was fabricated to simulate the blast environment produced during the firing of an antitank weapon from an enclosure. Muffs were used as hearing protection.

This introduction explains the need for this study, describes the basic approach, and summarizes the major tests accomplished. This introduction is in three parts.

A. Background

B. Discussion of the Walk-Up Study Paradigm

C. Test Summary

A. BACKGROUND

The impulse noise produced by Army weapons is called blast overpressure (BOP), the change in air pressure that occurs as a result of an explosion. For the purposes of this study, BOP refers to overpressure experienced by a crew member of a mortar or artillery piece when that weapon is fired. As such, BOP is an expected part of the training environment of many soldiers and is considered an occupational medicine concern. The soldier is exposed to BOP in peacetime and in war. In fact, the peacetime mission may have the greatest impact on hearing in a society as soldiers are continually enlisted, trained, and released back into civilian life.

It is widely known that exposure to blast waves results in injury to gas containing structures (Chiffelle, 1996; Dancer et al. 1981; Phillips et al., 1982; Richmond et al., 1968; White, 1968;

and White et al., 1971). The difficulty of transferring energy across the tissue/gas interface and the compressibility of air-containing organs are the important factors (Chiffelle, 1966, and Jonsson, 1979). The most sensitive organ is the ear, which might be affected in two ways. At higher levels of blast, the tympanic membrane can rupture with a variety of consequences ranging from a minor problem to severe pain, vestibular disorientation, tinnitus, and hearing loss (Faugere et al.; Hirsch, 1968). At lower levels, the hearing function of the inner ear may be impaired particularly with repeated stressing. The ear may be conceptualized as a device for changing acoustic energy into neural impulses. A freefield pressure wave imparts energy to the inner ear via the resonant ear canal, and the mechanical coupling of the eardrum and ossicular chain to fluid-filled sensory apparatus (Tonndorf, 1976). As a result, the ear is more sensitive at certain frequencies such that different pure tones of equal acoustic energy may give markedly different response. The ear is tuned to respond best to the important frequencies of normal speech (0.5-4 kHz) and acoustic energy delivered above or below this range will have less noticeable effect. Therefore, in assessing the injurious potential of a freefield pressure wave, consideration must be given to frequency content (Price, 1982, and Smoorenburg, 1984). If the auditory system is driven too hard, it is possible to damage the organ and reduce hearing sensitivity. If the overload is modest, the change might be only temporary, lasting minutes to hours, and is likely a reversible, ultrastructural or biochemical event. More severe noise will result in permanent loss of hearing with microscopically evident loss or derangement of the neurosensory hair cells (Henderson et al., 1974, and Spoendlin, 1976).

Blast can also injure nonauditory structures such as the respiratory and gastrointestinal tracts (Chiffelle, 1966, and Phillips et al., 1982). At intense casualty level blasts, pulmonary injury with arterial air embolization can cause death almost immediately. Respiratory failure from pulmonary contusions or complications of gastrointestinal injury can follow over hours or days. The risk of nonauditory injury following repeated exposures at the lower BOP levels experienced by gun crews had not been systematically addressed before 1978. This study is part of a US Army Medical Research and Development Command (now US Army Medical Research and Materiel Command) BOP research program started in 1978.

The current guidelines on human exposure to BOP are given in MIL-STD-1474C, "Noise Limits for Army Materiel." The portion dealing with impulse noise, discrete noise events of which BOP is a subset, is based primarily on data from the 50's and 60's on human exposures to rifle fire without hearing protection (Coles et al., 1968, and TB MED 251, 1972). It rates the hazard of hearing injury in terms of number of repetitions, peak pressure, and an arbitrary duration term, the B-duration. This term is the length of time that the overpressure fluctuations exceed a level 20 dB down from the peak (ambient +10% of peak), Figure I-1. The MIL-STD-1474C also attempts to account for the protection afforded by hearing as an effective reduction in peak level. The use of either ear plugs or muffs is called single-hearing protection (SHP); whereas, the use of both is called double-hearing protection (DHP). There are four types of plugs and at least ten makes of ear muffs available to the soldier (TB MD 501, 1980). These systems vary in ease of use, comfort, and effectiveness. Ideally, when assessing the efficacy of any hearing protector, one must consider that the attenuation of the freefield signal by the device has a spectral component. However, the current Army standard for impulse noise exposure attributes a fixed 29-dB reduction in peak level for any SHP with an additional 6.5-dB reduction for use of DHP. There is no recognition of the wide range of efficacy of various types or makes of protectors and no attempt to account for either the spectral sensitivity of the ear or the spectral aspect of attenuation.

Experimental evidence suggests that one must account for the spectral distribution of both the properties (Patterson et al., 1977) of a hearing protector and the acoustic energy of the noise in assessing the relative hazard (Price, 1982, 1983, and Smoorenburg, 1984). In contrast to MIL-STD-1474C, corresponding standards of the United Kingdom, West Germany, and the Netherlands use an approximately equal energy basis for assessing the noise hazard (Pfander, 1979, 1984, and Smoorenburg, 1982, 1984); that is, the total energy of the BOP is considered as important. Much of the data base for these standards has been obtained from human exposures to rifle fire that has spectral energy peaks around 3 Hz. On the other hand, large caliber artillery BOP and the antitank BOP in chambers have a much lower frequency peak power component, often below 100 Hz. Experiments have shown that the ear is less sensitive to this low frequency sound (100 Hz) than to a high frequency sound (1-6 kHz) of equal total acoustic energy (Buck,

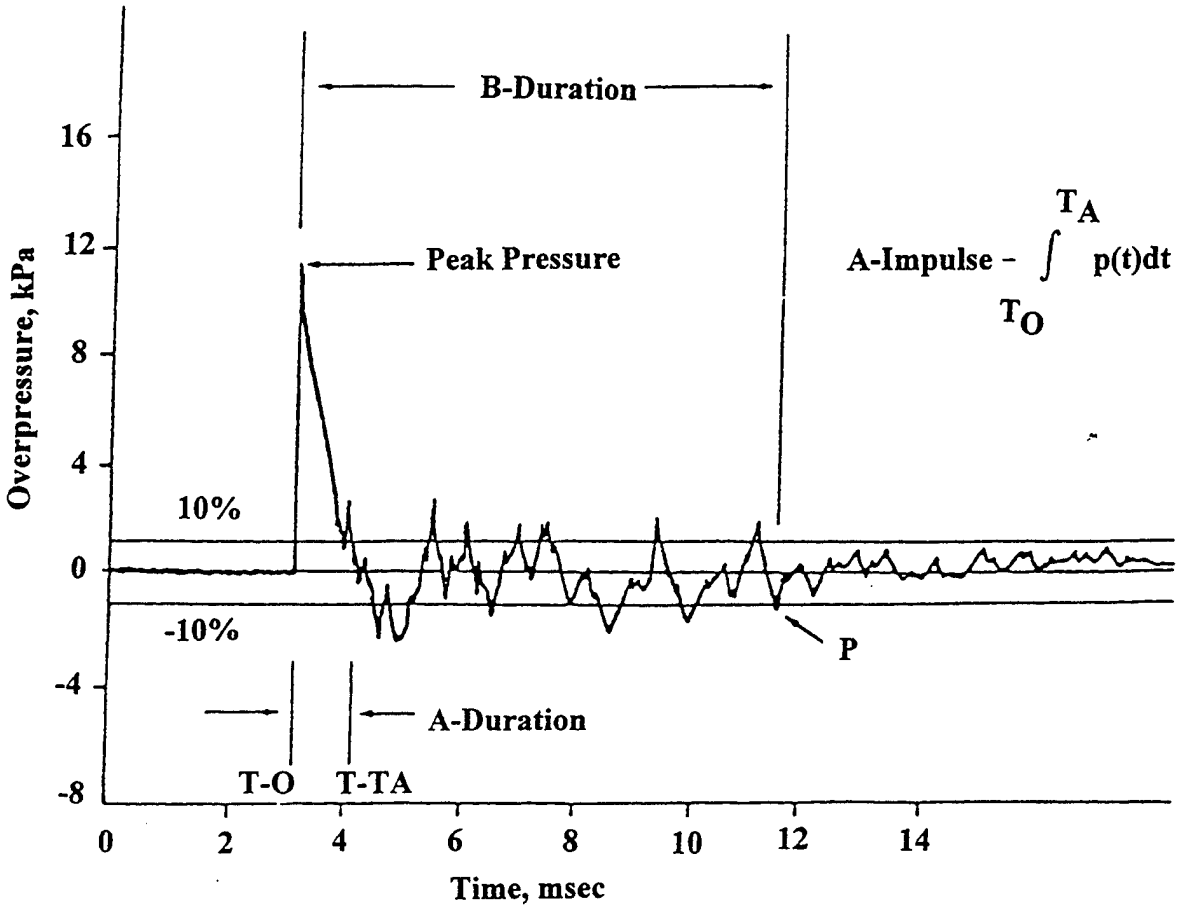


Figure I-1. Representation of a Typical Friedlander Blast Wave with a Nearly Instantaneous Rise from Ambient and Exponential Decay. The calculation of A-impulse is illustrated. The B-duration is from MIL-STD-1474C.

1983, and Price, 1983). The relative sensitivity of the human ear for various frequencies of noise is handled by a weighting network. This transformation for equating the spectral energy of noise is called the A-weighted curve. The A-weighted energy concept has some drawbacks but it is a step forward from a simple unweighted equal energy standard.

Application of MIL-STD-1474C to several new US weapon systems shows them to produce BOP above the Z-curve limit of that standard (Fig. I-2). While blast is hardly a new feature of weapons, several factors make BOP an increasing problem. Perhaps most important is the general increased awareness and concern over occupational health hazards and their potential cost to the individual and to society. Not only has our knowledge about the risks of BOP increased, but the modern soldier is exposed to higher levels than before. The BOP has increased principally because of the requirement for lighter, longer range weapons. These require more energetic propellants and often the use of a muzzle brake. (The brake is a baffle on the end of the gun barrel that deflects some exhaust gases back toward the crew. This deflection of exhaust gases reduces the need for heavy mechanisms and/or increased weight to oppose the recoil.) Unfortunately, the muzzle brake may increase BOP in the crew area several fold. Another important factor is crew proximity to the muzzle. This is critical for mortars where the crew may be within a meter or less of the blast source and for howitzers where US doctrine positions gunners alongside the breech and precludes the use of a long lanyard.

The USAMRMC is frequently requested to help the weapons developer/user community in evaluating the health hazard posed by the BOP of existing or prototype weapons systems. If the BOP exceeds MIL-STD-1474C, USAMRMC formulates alternatives including determination of acceptable crew positions and recommendations for maximum charge and number of rounds to be used in training. In the event these solutions fail, a man-rating study can be done. The longest and most important man-rating study was that for the M198 155-mm Howitzer firing its maximum charge, M203 (Patterson, et al. 1985). In essence, 59 volunteers were exposed in crew positions of

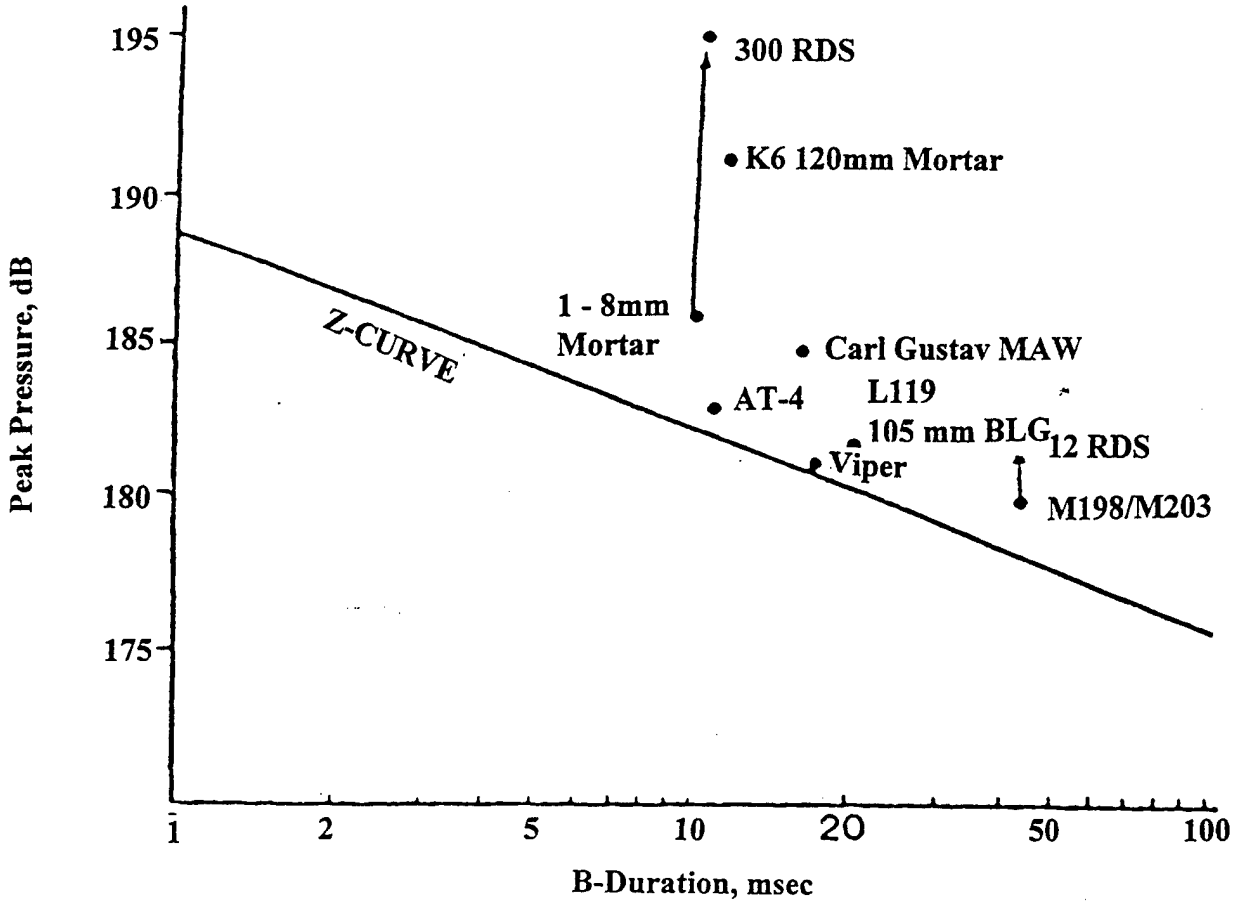


Figure I-2. Blast Overpressure of Some Current Weapons as it Relates to the Z-Curve of MIL-STD-1474C. Effective increase in level of increase in number is given as dB = 5 log(N).

the M198 to BOP in a progressive fashion to a maximum of 12 rounds of M203 charge. All subjects were carefully evaluated for auditory and nonauditory injury. None was found although the exposure was above the Z-curve limit and only SHP was used. This was accomplished using E.A.R.® compressible foam ear plugs. The M203 charge was then approved for use in training with up to 12 rounds daily with the E.A.R.® plug.

The results of the previous five-year study, using the RACAL® muff, again demonstrated the conservative nature of the Z-curve for several different freefield waveforms. More than 270 subjects were used under a protocol almost identical to the protocol used for the nonlinear plug study reported in this report. The RACAL® muff provided adequate protection up to levels of 188 dB, far above the Z-curve.

The US Army is evaluating several classes of new weapons. These include: a light 105-mm howitzer, a 120-mm mortar, a replacement 81-mm mortar, improvements to the M109 155-mm self-propelled howitzer, the concept of an ultralight towed 155-mm howitzer, and new shoulder-fired antitank rockets. The blast overpressure (BOP) limitations based on MIL-STD-1474C are important considerations in the system design and evaluation. The BOP could become a major road block to an otherwise desirable option. While the BOP exposure limits are given for training purposes only, training sets the probability of success for the combat mission. If modifications to the training environment are made, which could result in exposing soldiers to acceptable levels of BOP in peacetime; whereas, combat operations might result in significantly greater BOP exposure, realistic training might not occur. Experience with the M198 man-rating study, our generic freefield study, and a better general knowledge of the spectral sensitivity of the ear suggested that MIL-STD-1474C is conservative for large caliber weapon noise and probably conservative for antitank launchers fired from an enclosure. Therefore, there is great interest in relaxing the BOP limits on this class of weapons. Doing this on a case-by-case basis is not at all efficient, but until now, a broadly applicable nonauditory exposure limit has been lacking.

Therefore, the general approach of the previous study was to use several different waveforms. Since in the freefield the shapes of the waveforms are affected by distance, three separate study

distances were used. For the testing of the nonlinear plugs, the 3-meter distance was used. For the reverberant simulation, a waveform similar to the actual firing a Carl Gustaf from a bunker was used.

The auditory end points (failure criteria) used in this study were based on a temporary threshold shift (TTS). This is a transitory elevation of the hearing threshold as reflected in an audiogram. The TTS has been often used as an indicator for auditory hazard. For example, TTS was used in the development of the CHABA impulse noise damage-risk criterion (CHABA, 1968). This criterion was based on an explicit assumption that the permanent threshold shift (PTS) after a career of noise exposure would be no greater than the TTS from a single exposure. The approach used in establishing the protocol for this study did not make this strong assumption. The assumption used was that the appearance of a moderate TTS indicates that the threshold of unacceptable auditory injury is "near." That is, if the exposure gets much more severe, then large TTS's and, perhaps, PTS's are likely to occur. Most of the TTS research in humans was done before 1968. This research is reviewed in Kryter (1970). Historically, TTS's of 40 dB or less have been commonly associated with complete recovery (Kryter and Garinther, 1966; Ward et al., 1961). More recently, Pfander and his co-workers in West Germany have reported a long series of studies of military personnel exposed to weapon noise during training (Pfander et al., 1975). They have concluded that any TTS that persists beyond 24 hours indicates an unacceptably hazardous exposure. While their primary focus was on the time required for a TTS to recover, they provided data relating TTS measured soon after an exposure to impulse noise and the time required for recovery to normal hearing (Pfander et al., 1980). These results show that for TTS's of less than 25 dB, recovery occurs in less than 24 hours. Long recovery times are seldom associated with TTS's less than 35 dB. There is general agreement that infrequent exposures resulting in TTS up to 25 dB are unlikely to produce PTS (NATO RSG.6, 1987). With the freefield studies completed at the BOP Test Site from 1989-1993, these assumptions were not contradicted (Johnson, 1994).

The growth of the average TTS with increasing impulse noise exposure intensity has been reported to be approximately a 1-dB increase in average TTS for each decibel of increase in peak pressure (Kryter, 1970). This relationship holds for most of the human data available. However, individual data do not show this

simple relationship. Individual subjects tend to show very little growth up to some intensity and then a much more rapid growth of TTS as intensity increases further (Ward et al., 1961). Occasionally, the TTS can double in as little as a 3- to 5-dB increase in peak pressure. Growth of TTS with number of impulses shows a similar average trend, i.e., a 3 dB per doubling of number (Kryter, 1970). Individual data are not available for increases in number of impulses, so it was not clear whether rapid growth of TTS with increasing number is likely.

In addition to effects on hearing thresholds, exposure to noise can damage the sensory receptors in the inner ear (Henderson et al., 1974; Jordan, et al., 1973; Alexander and Githler, 1951). Most often, the loss of these receptor cells is associated with PTS. However, in animal experiments, receptor cell losses have been observed without any measurable PTS (Henderson et al., 1974; Hamernik et al., 1988). When the noise exposure is to impulse noise, these receptor cell losses with no PTS occur when a large TTS has slowly recovered to normal hearing. This finding supports the conclusion that moderate TTS's that recover rapidly are not likely to be associated with permanent injuries while large TTS's should be avoided.

B. DISCUSSION OF THE "WALK-UP" STUDY PARADIGM

One key issue in accomplishing this study is the safety of the individual subjects. A simple approach is to select a reasonable exposure condition under which training is desired and then to test a large number of subjects. Unfortunately, some very sensitive subjects might receive substantial permanent hearing loss from that one exposure. The walk-up concept attempts to avoid this problem. Much like walking up to a raging bonfire until it is too hot to face, a subject could walk up to a series of explosions until his hearing was changed. The same result can be obtained by keeping the subject in the same location with respect to the fire, or blast, and changing the strength of the fire or blast in small steps. It is the latter approach that was used in this study. For several different distances between the location of the blast with respect to the subject, the strength of the blast was increased until an effect was observed or the subject safely passed all the conditions. Once an individual subject showed a sufficient amount of TTS so it was clearly blast related, further exposure at that level was stopped.

C. TEST SUMMARY

1. Firing from a Bunker Simulator

The firing from a bunker simulation started in June 1994 and finished in June 1995. The RACAL® muff, modified to simulate a leaking muff, was used as the primary protector.

2. Nonlinear Plug

Starting in July 1995, there were two phases of testing accomplished using one distance (3-m) and three different types of hearing protection.

The first phase was at a 3-m distance with an A-duration of 1.5 ms. A nonlinear plug, designed at the US Army Aeromedical Research Laboratory (USAARL), was used as the hearing protector with the E.A.R.® foam plug as an alternative (or a backup) in case the nonlinear plug did not work for an individual.

The second phase was a repeat of the 3-m distance using a nonlinear plug designed at the French-German Research Institute of Saint-Louis, France as the primary protector. Again, the E.A.R.® foam plug was used as a backup.

II. METHODS

A. GENERAL

The Firing from a Bunker Simulator Study (reverberant waveform) was conducted from July 1994 to May 1995. The Nonlinear Plug Study (freefield waveform) was conducted from July 1995 through November 1995. Both studies were done at the Blast Overpressure-Kirtland Test Site (BOP-KTS) in New Mexico. Under a contract conducted for the USAMRMC, EG&G was responsible for preparation of the study site, data acquisition and reduction, and all tasks not related to subject recruitment. The responsible investigator was Daniel L. Johnson, Ph.D., with Donald Peterson, Ph.D., substituting during periods when Daniel Johnson was absent from the site. The USAMRMC contracting officer's representatives, James Patterson, Ph.D., of USAARL until 30 September 1995, and M.A. Mayorga, M.D., LTC, MC, of WRAIR from 1 October 1995, maintained scientific oversight. The protocols used in the studies were reviewed for scientific content and human use considerations both by EG&G's Institutional Review Board (IRB) and a Human Use Review and Regulatory Affairs Division (HURRAD) at the USAMRMC. The Office of the Surgeon General's Human Use Review Officer at Fort Detrick had final approval of all protocols. The complete protocols and all amendments are available from the Department of Respiratory Research, WRAIR, or Biophysics Operation, EG&G MSI. EG&G provided on-site medical support and a medical monitor via a subcontract with the Lovelace Medical Center.

B. VOLUNTEERS

Active duty soldiers were asked to volunteer. Only males were allowed to volunteer for the reverberant study. Females were allowed to volunteer for the nonlinear study, but because the subjects were drawn from the all-male pool at Ft Sill, none of the subjects were women.

In coordination with the Training and Doctrine Command (TRADOC) and the Total Army Personnel Command (PERSCOM), a military installation approved by PERSCOM was identified as the source of volunteers. Volunteers participated on TDY orders while en route to their first unit assignment.

The request for volunteers was made to company or battalion-sized formations at approximately five weeks before the end of the

training cycle. The volunteer statement (Appendix A) was used. After being briefed on the study procedures and before signing the consent form, subjects were given a test to determine that they understood the risks and that they were free to withdraw anytime without penalties. Volunteers who were in good military and academic standing had their medical records initially screened by the recruiting officer and approved by PERSCOM for subject suitability. The goal for the reverberant study was 60 subjects and the goal for the Nonlinear Plug Study was 24 to 28 subjects. Volunteers were taken in groups of 10 to 14 and they participated for approximately 45 days.

Further, to minimize an already very low risk of nonauditory injury, all candidates were medically screened. The individual must have had a normal expiratory spirogram (to rule out occult lung disease), posterior-anterior and lateral chest roentgenograms that showed no evidence of blebs or bullae, and a negative stool guaiac. No subject was used if he had a history of respiratory problems to include but not limited to: pneumothorax, allergic rhinitis, sinusitis, or emphysema. Each candidate was screened by an electrocardiogram and was excluded from the study if it was abnormal or if he had a history of valvular heart disease or cardiac dysrhythmia. Serial stool guaiacs were done as often as possible during the reverberant study, but were only done once during the Nonlinear Plug Study. A potential volunteer had to demonstrate that he could undergo laryngeal examination without difficulty. Local anesthesia was used to perform an adequate study and anyone with a history of allergies to such agents was excluded from participation. This periodic examination was part of the non-auditory safeguards of the study design.

The volunteers must have demonstrated hearing within normal limits in the experimental right ear. They must have had pure tone thresholds between -20 dB and +10 dB re: normal hearing for frequencies 1,000 Hz and below, and between -20 dB and +20 dB for frequencies 2,000 Hz and above. The left, or nonexperimental, ear must have met the H-1 Profile standards of AR 40-501 with slight modifications, specifically, thresholds no poorer than +25 dB at 500, 1,000, and 2,000 Hz, +30 dB at 3,000 Hz, and +45 dB at 4,000 Hz and above. The allowable threshold levels for the left ear allowed participation in the study by volunteers who showed evidence of unilateral high frequency hearing loss, such as that often found in individuals with a history of noise exposure

associated with firing rifles. To exclude those volunteers would have restricted participation to a biased subject sample rather than the general population of soldiers for whom the study was intended. The right ear was always designated as the experimental ear. Therefore, the computerized audiometer used in the study was designed to test that ear first.

The left ear was well protected so there was little risk of damage to that ear during the study. First, the left ear was always protected by E.A.R.® foam plugs. Further, the level of the impulse noise for the Nonlinear Plug Study was reduced, to some extent, on the left side by the "shadow" effect of the head. For the reverberant study, the left ear was also protected by the unmodified RACAL® muff.

Because of the inherently noisy nature of military training, the subjects were instructed on the need to protect their hearing during the remainder of their training, as any hearing loss incurred before their inclusion in the study might disqualify them. Each subject was examined to ensure his ability to effectively wear E.A.R.® compressible foam ear plugs of the type used in the study and ear muffs of the type used for ear protection and audiometric testing. Once on-site for the experiment, each subject was trained on the proper method of inserting the E.A.R.® foam plugs to obtain optimal protection.

In addition to the physical examination and audiometric tests described above, each volunteer underwent an otoscopic examination and acoustic immittance tests, including tympanometry, before being accepted for the study. Evidence of middle ear pathology on these procedures precluded participation unless the condition(s) could be alleviated. The presence of middle ear pathology with conductive hearing loss could contaminate the data and might have placed the subject in jeopardy if the conductive loss cleared.

Before graduation from training, a final selection of volunteers was made based on a review of the medical records and cadre recommendations. Subjects that were selected received orders sending them on Temporary Duty to BOP-KTS for a 45-day period, following which they went on to their first unit assignment. Upon arrival at Kirtland AFB, BOP-KTS, volunteers were given a physical exam and audiometric evaluation to verify that they met the screening criteria for participation in the study. While at

Kirtland, they were under the supervision of the on-site COR stationed there as a permanent party. The on-site COR arranged transportation, saw to the administrative requirements of the volunteers, and oversaw an ongoing physical training program. If a subject withdrew from the study, he was sent to his duty assignment as soon as possible. However, his record in no way was to reflect negatively on his performance. Subjects were allowed to stop at any time and not be exposed to the next step. An elective failure was considered to occur at this point. Additional exposures at a lower intensity level than the next step at equal or lower energy of the next step were permitted if agreed to by both the subject and the principal investigator.

C. PROCEDURES

Before any exposures to BOP, at least eight baseline audiograms for each subject were taken. The average and standard deviation of at least eight of these audiograms were used as a master baseline. This master baseline was then used as the reference to calculate TTS after each exposure. The master baseline was also used as a reference for the daily preexposure audiograms to determine whether they were acceptable. The pooled standard deviations estimated from these baseline audiograms were used in calculating the failure criteria for that volunteer. Any volunteer who produced a pooled standard deviation greater than 4.0 in the test ear was normally excluded from the study. A pooled standard deviation of 4.1 was allowed in a couple of cases when most of the variance came from the audiometric frequencies of 125 Hz or 8000 Hz.

Each volunteer was given training on the proper use of both types of hearing protectors (the nonlinear plug in the test ear and the E.A.R.® foam plug in the nontest ear) to be used in the study before any exposures to BOP. At least eight attenuation tests of both earplugs were completed during this training. The full baseline for the E.A.R.® foam plug for the right (test) ear was dropped as a routine requirement and developed only in the few cases that the subject would need to use the plug as second-level hearing protection. The average and standard deviations calculated from these tests were used as norms for the attenuation achievable by each volunteer. These were used to judge whether a preexposure attenuation was acceptable.

The first exposure for any subject at any distance was below the level of the Z-curve of MIL-STD-1474C (see Fig. I-1). All overpressure measurements were made according to the recommendations of the US Army ad hoc Committee on Blast Overpressure Measurements. Overpressures were recorded at the subject's exposure distance for each blast and full data records were maintained for later analysis.

Subjects were not exposed if they had symptoms of an upper respiratory or gastrointestinal illness. The medical monitor decided when a subject could return to the study. If a subject had medical complaints possibly related to blast exposure, the medical monitor and USAMRMC investigators conferred as to the appropriate course of action. Initial evaluation was done (at no cost to the individual) at the Lovelace Medical Center (under contract to EG&G) with referral to the Air Force Hospital at Kirtland AFB in Albuquerque, NM, as indicated.

The logic of how an individual subject was exposed to a sequence of conditions is as follows: Basically, an allowable matrix of exposures was determined for any distance (D). The subject started at the lowest number (N = 6 or 1), an initial intensity (A = 1), and first-level hearing protection (FLHP) (H = 1). A pass for any condition E (D, A, N, H) allowed the subject to proceed to a more energetic condition by first going up (increasing intensity, A) in the matrix. When the maximum intensity was reached, then the number, N, was increased. The number, N, was always set to 6, 12, 25, 50, and 100 for freefield and 1, 2, or 3 for reverberant. Intensity, A, was set to represent approximately a 3-dB increase of peak level for each increase of A. Once a subject had failed at some condition E (D, A, N, H), then that peak level (A) and greater peak levels were not allowed for that level of hearing protection (H). The numbers of detonations (N) could still be increased. Appendix D outlines how an auditory failure limits the allowable exposure conditions. After completing the allowable exposure for ear muffs, occasionally, E.A.R.® foam plugs, which represent an improved level of protection, were used to retest the exposure matrix. A subject was allowed only one exposure condition each day.

Before each day's exposure, a general medical history and physical examination was performed by trained medical on-site personnel. Evidence of abnormal middle ear function could have

caused a subject to be withheld from further exposures until the problem had cleared. Next, the subject had to perform two automated tracking audiograms (ATA) that were within 5 dB of his baseline audiogram average. For the Nonlinear Plug Study, the subject then fit himself with a nonlinear plug (right ear) and an E.A.R.® foam plug (left ear). For the reverberant study, the subject used the E.A.R.® foam plug and RACAL® muff for his left ear and the modified RACAL® muff for his right ear. The experimenter assisted the subject in fitting the ear plugs only, if necessary, to insure appropriate attenuation as indicated by his baseline tests. The efficacy of the protection was tested. The real ear attenuation test (REAT), in which the difference in a subject's hearing threshold with and without a protector was used as the hearing protector's attenuation for the nonlinear plug and the E.A.R.® foam plug. Because of fitting problem with the nonlinear plug, an additional procedure was started early (after intensity Level 1) in the exposures of the subjects using the French No. 1 plug. There was concern that a good seal of the flanges with the ear canal was not occurring for some subjects. Because it was determined by the investigator that the procedure for checking the ear plug attenuation could not distinguish between the intentional leak through the filter and a leak around the flanges, a revised test procedure was instituted. The revised procedure consisted of adding the following test. After a subject was tested using the French No. 1 plug and his baseline was shown to match his previous baseline, a small wire was inserted to block the 2-mm diameter hole in the rear of the ultrafit earplug. The subject was tested again at 250, 500, and 4000 Hz. If the attenuation increased by at least 10 dB at two of these frequencies and at least 5 dB at the other frequency, the plug was considered to have a good seal. The wire insert was removed and the subject was ready for his exposure. In addition, approximately one-half way through the French No. 1 Plug Study, the subjects were instructed to place their finger over the open end of the ultrafit plug and to try to see if they could detect a difference in attenuation of someone's voice. They were advised to do this test whenever they thought the plug might have moved.

This testing guarded against allowing the volunteer to be exposed to the intense noise with either an improperly fitted and, hence, ineffective plug, or an overly fitted plug resulting in overly effective hearing protection. The problem of using an overly effective fitted device is that such occasional abnormal attenuation defeats the purpose of the "walk-up" approach. A subject might have been susceptible to a certain exposure

condition. However, because he passes this condition due to the abnormal attenuation, he is exposed to the next higher exposure condition. This next higher condition may cause an excessive temporary threshold shift (TTS) if his hearing protector attenuation returns to normal.

The hearing protectors were adjusted and tested until an appropriate level of noise attenuation was obtained (±5 dB with respect to the subject's baseline).

The subject(s) was positioned on the exposure pad as described below. Some number (N) of charges of weight (W) were set off either at 1-minute intervals for the Nonlinear Plug Study or at 2.5-minute intervals for the Firing from a Bunker Simulator Study. The subjects were given a countdown of "Ready, 5, 4, 3, 2, 1" before each blast, so they could tense up or relax as they saw fit. There was always a staff employee, usually the PI, who acted as the shepherd. The shepherd would check the subjects after each blast. At the finish of the exposure sequence of N charges, the subjects would quickly walk to the audiometric booths, taking off their gear as they walked. Beginning at approximately 2 minutes following the exposure, the ATA was repeated to detect any TTS that might have been induced by noise exposure. The subject's TTS was also determined at 20 minutes and 1 hour after exposure. If the TTS at 1 hour was back to baseline (±10 dB), then the subject was excused from further audiometry testing. Otherwise, an ATA was performed at 2 hours and, subsequently, as needed. Occasionally, the 20-minute or the 1-hour audiogram was used as an indication of failure when clearly, the TTS was growing with time. Then, many audiograms were taken to ensure that the time when recovery started was identified.

The first audiogram obtained post exposure normally provided the basis for a "pass/fail" decision for that exposure. The subject was considered to have passed or failed the noise exposure condition based on the algorithm in Figure II-1. The logic for the critical TTS decision is detailed in Appendix D. If a subject incurred a TTS greater than the critical value, i.e., a "failure," he could not be exposed for at least 2 days. If a subject's TTS of greater than 10 dB persisted for more than 24 hours, i.e., did not return to baseline, that subject was excused from further exposures and referred for appropriate medical and audiological evaluations. Subjects with excessive TTS (>40 dB) and subjects with TTS that grew with time could also be dropped from further exposures. However, no subjects were dropped for this reason.

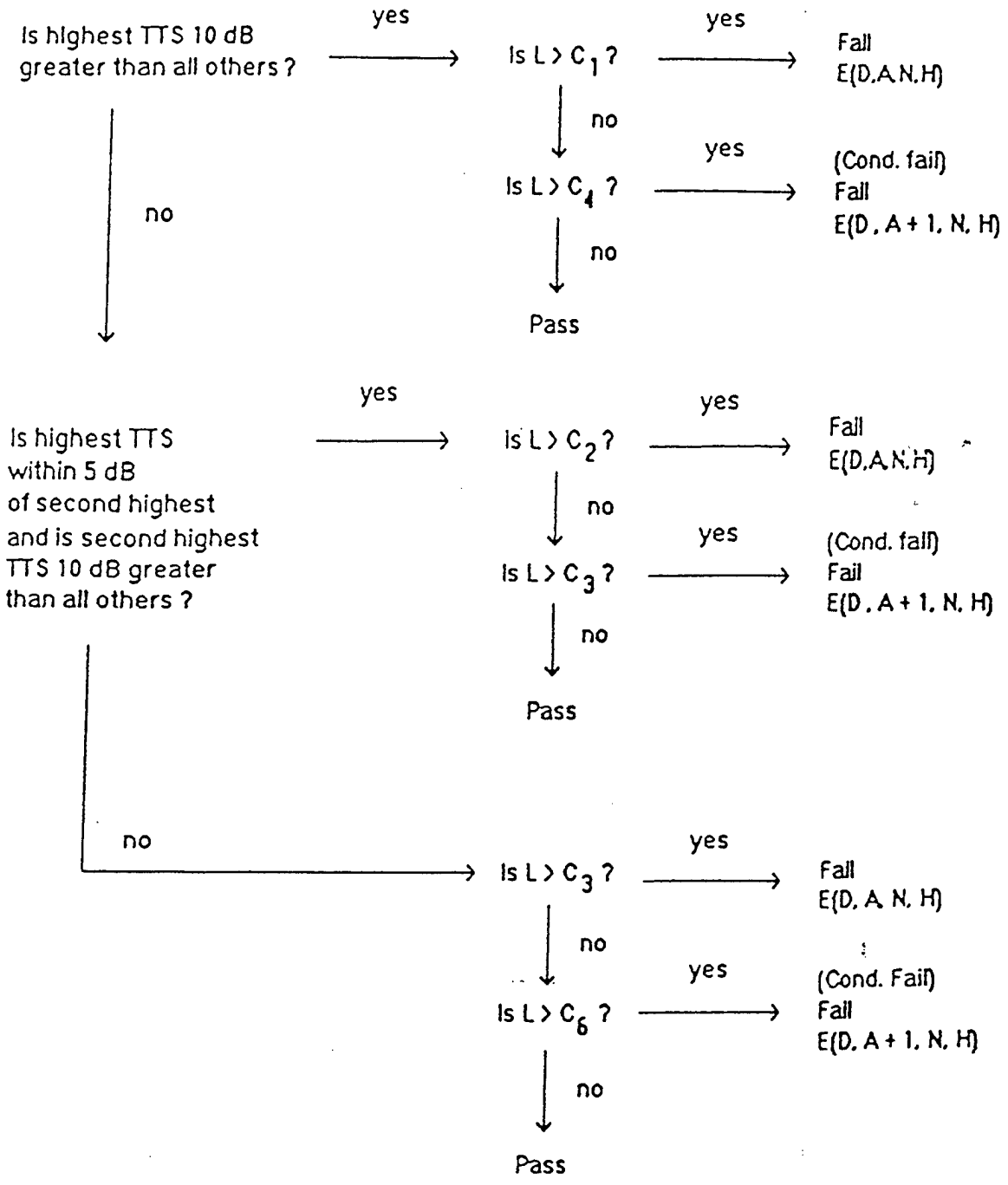


Figure II-1. Decision Tree for Critical TTS Pass/Fail Decision.

The fundamental audiometric failure criterion was set as a TTS of 25 dB at any frequency. For subjects with audiometric variability, ≥3 dB, a small adjustment was made that elevated this level by at most 2 dB, see Appendix D for details.

In order not to unduly over expose subjects who were just below this 25-dB figure, the concept of a conditional failure was used. A conditional failure was defined if TTS exceeded 15 dB.

For subjects with audiometric variability of ≥2 dB, a small adjustment was made that elevated this level from 0 to 2 dB, see Appendix D. When a subject was a conditional failure, his next step was to a lower intensity at double the number of shots.

In the previous freefield study, routine laryngoscopic examinations were initially given after all exposure conditions closest to the nonauditory limits for six exposures. Additional examinations could be given at any condition that the investigators or medical monitors deemed to be prudent. A positive laryngoscopic finding on these exams resulted in a repeat exposure starting one energy level below the one that resulted in a positive finding. Two positive laryngoscopic exams at the same exposure conditions or adjacent conditions resulted in a nonauditory failure in the lower energy condition. A nonauditory failure resulted in that subject being precluded from any exposures at the same or higher intensities. Intermediate larygnoscopic exams were given after the most energetic exposure for the Firing from a Bunker Simulator Study.

After negative results in the early stages of the previous 3-m distance, the IRB allowed these intermediate tests to be dropped. Therefore, only the pre- and postexposure overall study participation laryngoscopic exams were taken on most of the subjects in the Nonlinear Plug Study.

After a subject had completed post-exposure testing, he was informed of the next day's schedule and returned to his place of lodging. He was normally free of further duty assignments except physical training.

D. EXPOSURE SIMULATIONS

1. Firing From a Bunker Simulator (Reverberant Waveform)

The reverberant waveform typical of firing a rocket launcher from a bunker was simulated by using an all-steel enclosure with volume of 18.2m³. This volume was obtained by moving the adjustable partition (see Figs. II-2 and II-3).

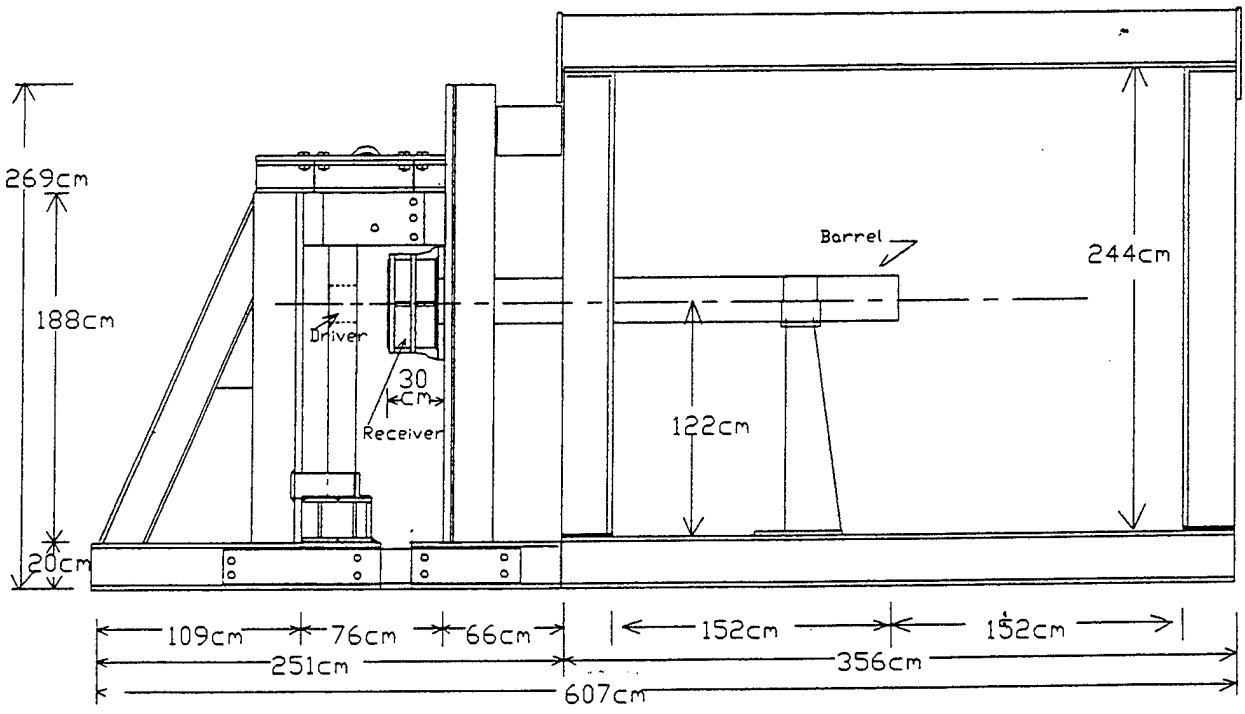


Figure II-2. Firing From a Bunker Simulator (Side View).

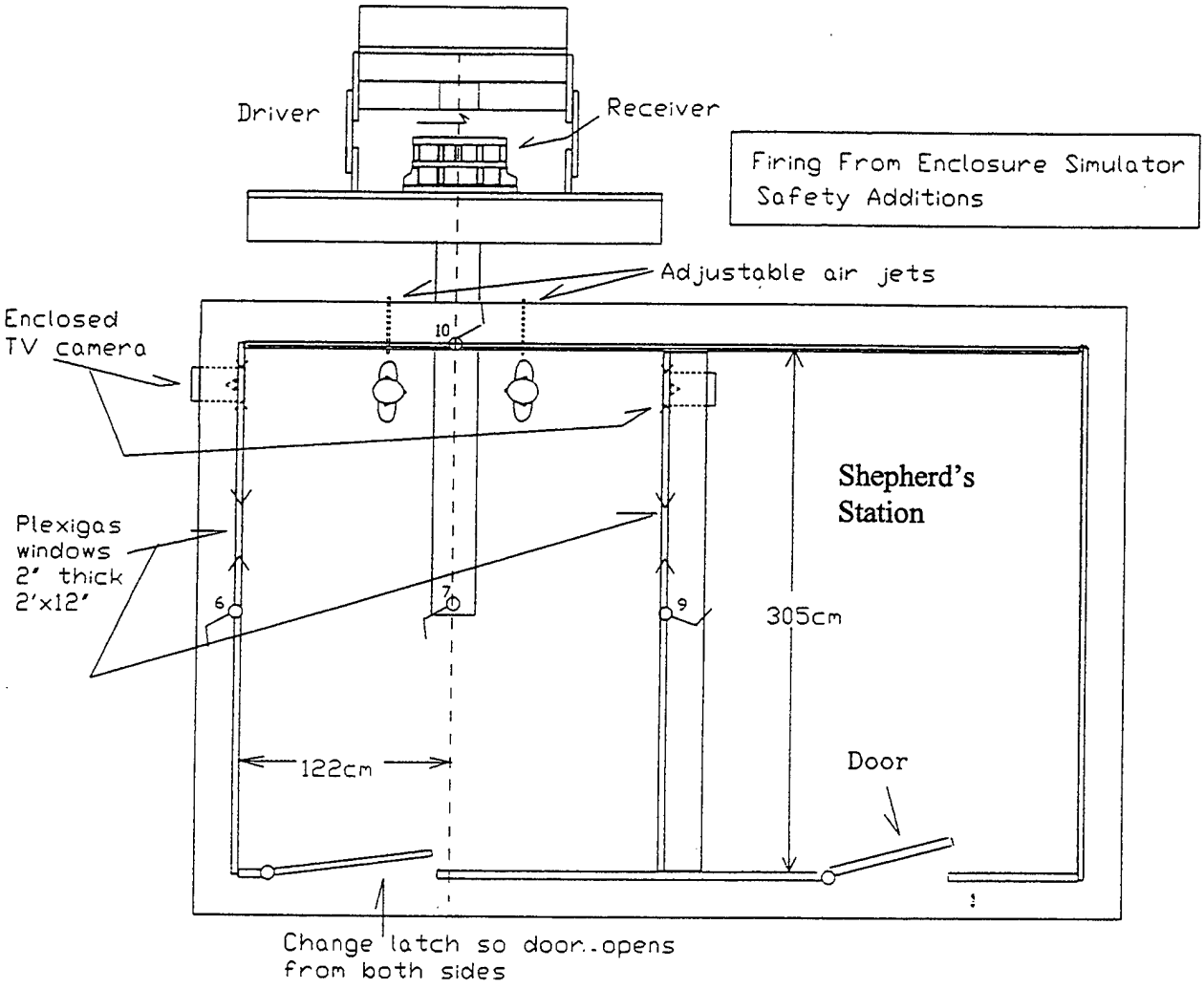


Figure II-3. Firing from a Bunker Simulator (Top View).

A hole was cut in the wall directly opposite the door to allow the introduction of a 249-cm long 'gun barrel' constructed from a seamless high-pressure steel tube, 20 cm I.D. and 2.54 cm thick. This tube extended 152 cm into the chamber. The tube was horizontally mounted with its centerline 122 cm from the floor and supported inside the chamber by a 2.54-cm thick stand that consisted of a 46- x 33-cm base plate, a vertical member that decreased in width from 30 to 19 cm, and a barrel mount. The mount included a 30- x 16- x 2.54-cm support plate and a 15-cm wide by 1.27-cm support plate and a 15-cm wide by 1.27-cm thick band that surrounded the tube. The barrel extended 3 cm beyond the barrier wall and was surrounded by a 'receiver' constructed from a 30-cm length of 2.54-cm-thick wall high-pressure tubing. The receiver tapered from 42- to 41-cm I.D. It was surrounded by two radial and eight longitudinal gussets fabricated from a 2.54-cm plate to increase its hoop strength. A movable 1521- x 122-cm 'driver' section fabricated from two 15-cm thick plates of salvaged battleship armor was installed 15 cm downstream from the leading edge of the receiver. There was a 20-cm diameter hole cut in the slab of armor next to the receiver and was in line with the centerline of the gun barrel.

The simulators were operated by detonating a spherical charge of C-4 explosive in the mouth of the opening in the driver section for the back blast from a weapon firing simulation. The blast wave traveled down the barrel into the enclosure and was reflected off the back wall. The wave shape varied as a function of location in the room. The wave intensity was changed by changing the charge weight. The simulator was operated with the enclosure inertia vent doors open to reduce a quasi-static pressure rise and to eliminate explosive decomposition products.

The subjects sat facing each other. The center of their head was 33 cm from the front wall. The center of their ear canal was 167 cm above the floor (or 45-cm above the centerline of the barrel) and 83 cm from the side walls (or 39 cm from a vertical plane going through the centerline of the barrel). There were deadman switches under their seats, so if they got off their seats, the detonating circuit was interrupted. The PI was normally in the room on the other side of the partition (the shepherd station). There was a deadman switch in the shepherd station, so the person acting as shepherd could also interrupt the detonation circuit. The shepherd could also observe the subjects through a plexiglass

window. There were also closed-circuit TV cameras on the subjects so they could be observed by the physician assistant.

The test ear was always the right ear. About half the subjects sat so their right ear was next to the wall, and about half had their right ear facing away from the wall. Thus, the subjects were not allowed to change seats once the first exposure condition started. The test ear was afforded hearing protection by the modified RACAL® muff. The nontest ear was afforded protection by both the E.A.R.® foam plug and the unmodified RACAL® muff. Subjects wore shatterproof eye protection and the BDU fatigue uniform or the BDU uniform with a field jacket. The PASGT helmet was always worn. Because the subjects were inside the bunker, exposures were conducted in rain or snow. Testing was not conducted if the threat of lightening was present. Also, they were not conducted in high wind because of difficulties using the P.A. system for the countdown.

2. Nonlinear Plug Study (Freefield Waveform with a 1.5-msec Duration)

For the 3-m distance used in the Nonlinear Plug Study, the explosive charge of C-4 or det. cord was suspended in a 2-inch-thick tube with an I.D. of 22 inches. The subjects were positioned around the lip of the tube (see Figs. II-4 and II-5 for details). The center of the subject's right ear was kept either at 6 ft 6 inches from the lip (lowest five exposure conditions) or at 7 ft 8 inches from the lip (highest two exposure conditions). The outer portion of the ear canal was 6 inches above the plane of the lip in either case. The timing of the detonations was kept at 1-minute intervals. The subjects sat on stools with the test ear oriented normally to the direction of travel of the shock wave and they always wore hearing protection as described below. The nontest ear was afforded protection of E.A.R.® foam plugs. Subjects were given shatterproof eye protection and wore a T-shirt, the BDU fatigue uniform, or the BDU uniform with a field jacket. Exposures were conducted in light rain or snow, but not conducted in high wind, heavy rain, or if the threat of lightening was present. The PASGT helmet was always worn.

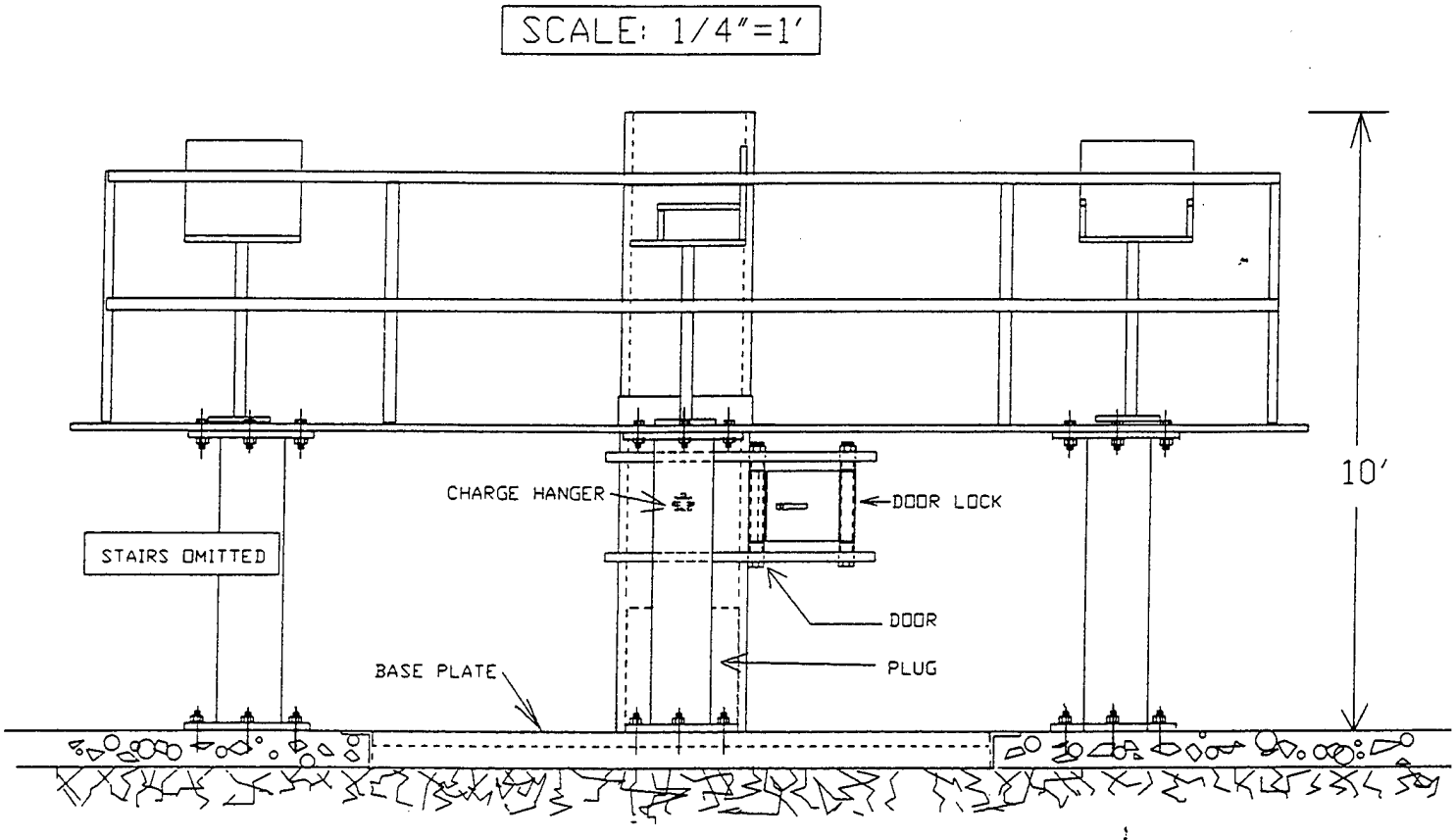


Figure II-4. The Mortar Simulator (Side View).

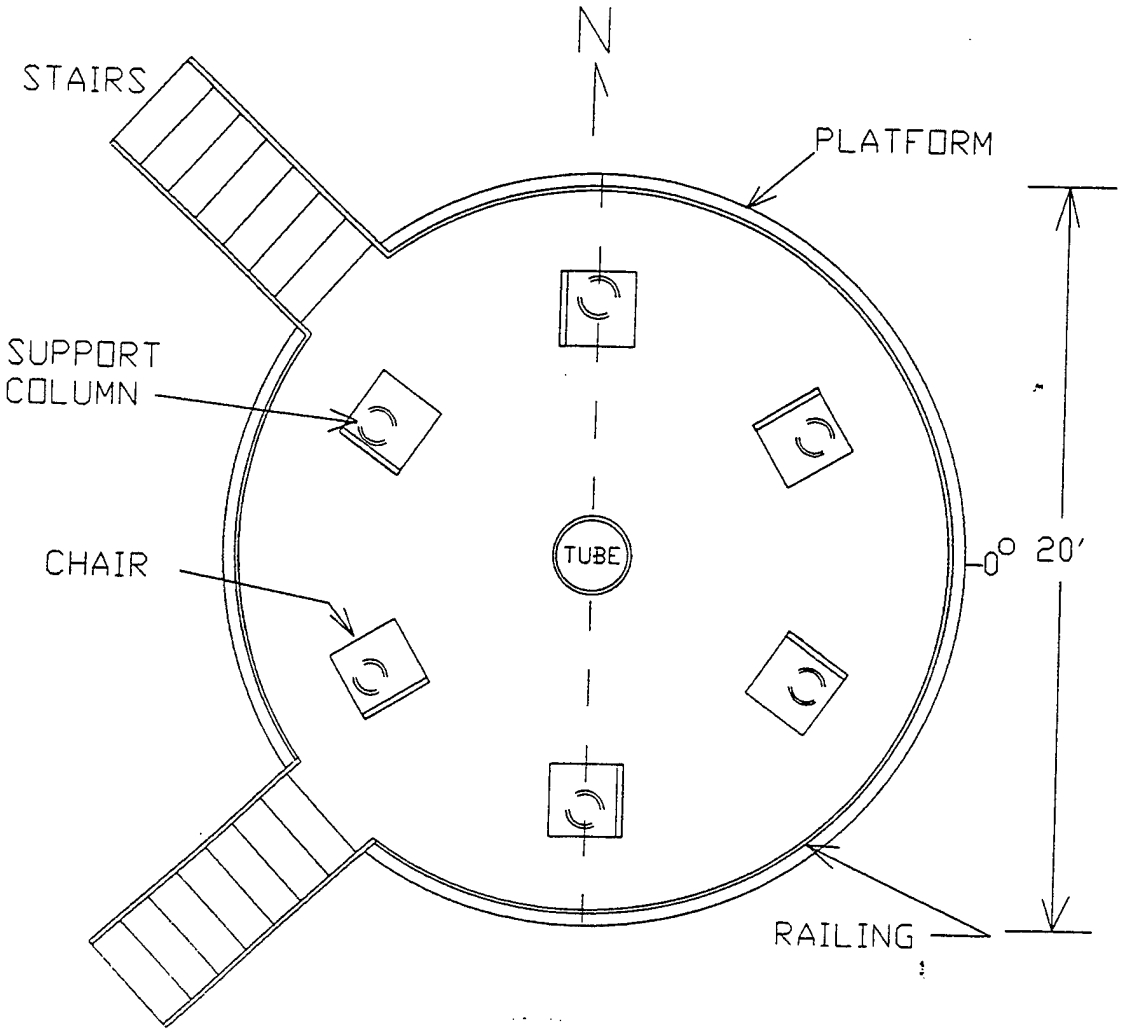


Figure II-5. The Mortar Simulator (Top View).

E. INSTRUMENTATION AND DATA ANALYSIS

1. Instrumentation

a. Blast Data Acquisition

The blast data acquisition system was a PC-based system that allowed the blast data to be stored on CD-ROM media. The pressure-time measurement test procedures were conducted according to the standardized techniques outlined in Patterson et al., 1980.

b. Audiometric System

The audiometric software subsystem was designed to allow flexibility in the way the audio tests were performed. Overlapping the subjects and tests allowed exposing up to 12 subjects per day. To accomplish this task, the audiometric test software was installed on two identical computers. The booth attenuators and buttons were tied to each computer through a custom-designed switching board. This allowed the user to decide which computer was controlling the booth. The computers were also linked on a network for the purpose of summarizing the daily audiogram scores onto one PC for archiving. In the event one PC failed, the other could be used to control all six booths until the backup computer could be connected to the booths. All data were written into ASCII files and at the end of the day transferred to the appropriate data base. A copy of all data bases will be archived on CD-ROMs for distribution once all the data are verified to be correct. Daily backups were made on 250-megabyte tapes.

The audiometric procedure, modified Bekesy tracking, was implemented to test up to six volunteers simultaneously. The system was patterned after the system used in the previous studies (Mozo et al., 1984; Patterson et al., 1985; Johnson, 1994). The PC controlled a separate HP programmable function generator, and programmable attenuator for each volunteer. The volunteers tracked their thresholds by a hand switch that controlled the direction of change in the programmable attenuator. The earphones used were TDH-49 elements mounted in a David Clark 9AN/2 ear muff for added noise isolation. The calibration of the earphones was accomplished using a Bruel and Kjaer (B&K) artificial ear with a flat plate coupler. The artificial ear incorporated a 0.5-inch B&K microphone

connected to a B&K 2636 measuring amplifier with output to the DAAS. The audiometric tests were conducted with the volunteers isolated in one-person, double-walled, double-floored audiometric rooms manufactured by IAC. The audiometric test system also collected and analyzed the earplug attenuation data.

The microphone's outputs were amplified and entered into an HP spectrum analyzer that was interfaced to a PC.

2. Data Analysis

For each exposure set, the blast overpressure (intensity) would be recorded and expressed in terms of peak pressure (kPa) and decibels (dB), A-impulse (kPa·msec), and B-duration (msec) as detailed in MIL-STD-1474C. The overpressure was also analyzed for total acoustic energy (P^2*s), A-duration (msec), and total area under the pressure-time history according to the recommendations of NATO Panel VII RSG-6. In addition, the energy in 1/3-octave bands was determined. Simple descriptive statistics, average median standard deviations, were used to characterize the exposures.

F. MEDICAL ASPECTS

1. Screening Evaluations

A review by the recruiter of the medical records of the volunteer subjects before their traveling to Albuquerque was done to eliminate those with a preexisting condition that might be aggravated by the study conditions. Any significant abnormalities in their records during this screening exam resulted in exclusion of that individual from consideration as a subject. In particular, a positive history for allergic rhinitis, recurrent sinusitis, chronic or unresolved pulmonary disease, or chronic or unresolved gastrointestinal disease resulted in exclusion. Significant or chronic disease of the ear(s) also resulted in exclusion.

2. Entrance and Exit Evaluations

After the subjects arrived at Kirtland AFB and at the conclusion of the study, each subject had a medical history and physical examination performed at the Occupational Medicine Department of the Lovelace Medical Center. This examination

included the medical history, general physical examination and additional clinical examinations that included an EKG, a single PA and a lateral chest film, a forced expiratory spirogram, a complete blood count, an SMA-12 or similar chemical profile, a urinalysis, and a stool guaiac. A laryngoscopic examination was performed and recorded for each subject by a qualified physician. The results of these examinations served as a record of the physical condition of each subject at the start and at the conclusion of the study period. The volunteer's medical records of examinations during the study are maintained at the BOP-KTS and appropriate entries were made in the volunteer's military medical records.

Those subjects who withdrew from the study before the conclusion of their scheduled study period received the exit examination to document their physical condition at the time of their withdrawal from the study.

3. Medical Monitoring

The medical monitor(s) was a licensed physician(s) on the staff of the Lovelace Medical Center. The medical monitor was assisted either by a physician assistant or a nurse practitioner. The physician assistant/nurse practitioner had Advanced Cardiac Life Support/Certified (ACLS) level training. An office/ examination room was maintained in the data acquisition/test building. He/she had immediately available a current emergency cart that met ACLS standards and was capable of caring for traumatic and cardiopulmonary emergencies (i.e., bandages to control bleeding and medications and defibrillator/monitor for cardiac arrest). He/she could refer problems to: the medical monitor or to an appropriate physician at the Lovelace Medical Center where a complete evaluation of the problem could be performed. The physician assistant/nurse practitioner was on-site during all subject exposures. The physician assistant/nurse practitioner performed a medical assessment of subjects on each morning of the study. These were performed to:

(a). Exclude those from that day's blast exposure who had some acute illness, such as an upper respiratory infection or gastroenteritis, which might be aggravated by this exposure.

(b). Detect those who may have some respiratory or gastrointestinal disorder that resulted from previous exposure to blast.

(c). Allow each subject to express particular concerns concerning his own physical condition, especially as this might relate to his continued participation in the study. This assessment included:

(1). Completion of a standard medical self-history form by the subject.

(2). Review of this medical self-history form by a physician assistant/nurse practitioner with commentary as appropriate concerning any positive answers.

(3). Brief physical examination of each subject to include: weight, temperature, pulse, respiratory rate, blood pressure, otoscopic examination of the ears, nose and throat examination, chest and heart examination, and abdominal examination.

Results of this examination were recorded on a standard form by the physician assistant/nurse practitioner. These were entered into a computer data base for further analysis.

Any subject with abnormal results was referred for evaluation to an Occupational Medicine physician at the Lovelace Medical Center. This resulted in exclusion of the subject from that day's exposure.

(d). A forced expiratory spirogram was performed on each subject. An abnormal result, not corrected by a repeat test, would have resulted in exclusion from that day's exposure. Furthermore, a follow-up PA chest x-ray and examination by a Lovelace Medical Center Occupational Medicine physician would have followed such an abnormal spirogram.

4. Laryngoscopic Examinations

Laryngoscopic examinations were performed by the ENT Department at the Lovelace Medical Center in the following manner:

(a). Fiber optic laryngoscopy was performed according to a standardized protocol after local anesthesia of the nasopharynx.

(b). The presence of hypopharyngeal or laryngeal petechiae was regarded as evidence of blast overpressure injury although petechiae are nonspecific indicators and may result from a number of causes. A subject displaying such petechiae was excluded from exposure until the petechiae cleared. The subject received subsequent examinations of the larynx until the petechiae cleared.

5. Medical Consultative Services

Medical consultative services were provided to subjects throughout the study. Subjects expressing a particular medical concern, especially if it related to their continued participation in the study, had the concerns recorded by the physician assistant/nurse practitioner on a standard form at the time of the morning medical examination. This concern was communicated by the physician assistant/nurse practitioner to the medical monitor, who could exclude the subject from that day's testing until appropriate counseling, which may have included referral to a specialist at the Lovelace Medical Center. Subsequently, depending on the subject's willingness to proceed with further exposure and the medical monitor's analysis of the situation, one of the following occurred: (a) return to the sequence of blast exposures, (b) exclusion from the study, (c) or referral to the Kirtland AFB Hospital for definitive follow up and/or treatment. In addition, the PI could also exclude a subject from testing for any reason.

G. PROTOCOLS

1. Firing from Bunker a Simulator Study

The protocol used was approved 21 April 94. No amendments were ever made to it.

2. Nonlinear Plug Study

The protocol used was approved July 6, 1995. On September 8, 1995, it was amended to allow different nonlinear plugs to be used.

H. Performance Assessment Battery (PAB)

A computer-based performance task, based on the Walter Reed Army Performance Assessment Battery (PAB), was given before each daily exposure and between the 20-minute and 1-hour audiogram. A baseline of eight tests was also established before the first exposure. The task consisted of four tests presented via a desk-top computer.

A PAB test was given to the subjects to assess any change in performance due to the blasts. The test was developed at WRAIR (Thorne, 1985). A subset of the total available Battery was used. The set consisted of four tasks displayed simultaneously on a computer screen. A mouse was used to control a cursor and one key on the mouse was used to make the appropriate decision.

A visual task required centering a moving symbol every so often. Not keeping the symbol within bounds resulted in points deducted.

A memory task consisted of six letters being initially displayed at the beginning of the session. Random letters would then come up every 10 seconds or so. The subject then received points if he could correctly identify whether or not the displayed letter was in the initial set. He lost points for incorrect answers.

An audio task consisted of two tones of different frequencies. A response after the high-frequency tone added points, a response after the low-frequency pulse subtracted points.

The math task was to select a correct answer to an addition problem. Unlike the other tasks, the rate of obtaining points was entirely determined by the speed of solving the problems. The tasks were performed at the same time. Three minutes was the test time selected. The subjects were allowed to train themselves for five to ten trials. A baseline of eight trials was developed. Each day of the exposure, the subjects did one test before each exposure and one test 35 to 55 minutes after each exposure.

I. OTOACOUSTIC EMISSION TESTS/SWEEP AUDIOMETRY TESTS

1. Otoacoustic Emission Tests

Otoacoustic emission testing was started after the 20-minute audiogram and continued on all subjects. A baseline with eight measurements was established before the start of the exposure sequence. A daily preexposure emission test was also given to the subjects of the Nonlinear Plug Study. The equipment used was the CUBDIS™ Distortion Product Measurement System manufactured by Etymotic Research. The supporting software was run on a 386 computer.

Two tones were generated and scaled so that the sound pressure in the ear canal was maintained constant as the frequencies were varied. The Etymotic ER-10B low-noise microphone was used to get the signals from the ear canal. A switchable amplifier having 0 dB, 20 dB, or 40 dB of gain was built into the ER-10B microphone preamplifier. The output of this amplifier was passed to the equipment where it is digitized. The software then averages the responses in real time in a synchronous manner.

The microphone signal consisted of the two primary sine waves at frequencies f_1 and f_2. The distortion products are assumed to be generated by the outer hair cells of the cochlea. The distortion product (DP) that was monitored with this system was the cubic difference tone at frequency $2f_1 - f_2$ where $f_1 < f_2$. The noise floor at frequencies near the DP frequency was also monitored and displayed as a control along the primary tone levels. Three levels of the primary signal were used: 60 dB, 50 dB, and 40 dB. Data were taken and stored for each of these three levels.

2. Sweep Audiometry Tests

To look at the hearing levels in more detail, constant level frequency scanning was used to determine the hearing levels from 125 Hz to 16 kHz using 64 points per octave. The equipment used is called "Audioscan" and is manufactured by Essilor, Cedox, France. These were given to each subject after the 1-hour audiogram. A subject who had a TTS was tested first. The first level scanned was the 0-dB hearing level. The subject held the button as long as he heard a sound and released the button when he did not hear a sound. The scanning speed was 10 sec/octave. When

the 0-dB level was finished, the 5-dB level was scanned for those frequencies where there was not a response at the 0-dB hearing level. The next step was to a 10-dB hearing level. This process was continued until an entire audiogram was completed.

J. DESCRIPTION OF HEARING PROTECTION DEVICES TESTED

1. RACAL® Muff

The RACAL® muff is designed to fit under the PASGT helmet. It has a separate built-in amplifier that controls a microphone/speaker combination in each ear cup. This allows communication at normal voice levels. The miniature speaker, however, cannot reproduce the blasts such that the levels under the muff are hazardous. Thus, the muffs act as a passive protection device in an intense blast field. They weigh approximately 490 g and the headband force is approximately 700-1800 g (see Fig. II-6).

2. RACAL® Muff (Modified)

The modified RACAL® muff is the same as the RACAL® muff except eight tubes with a 2.3-mm diameter hole have been inserted through the seal of the right earcup (Fig. II-6).

3. Rucker Plug

This plug is a modification of the triple-flange E.A.R.® ultrafit with a 2-mm diameter hole through its longitudinal axis. The modification consisted of putting a 3-mm long insert with a 3-mm diameter hole in the stem. The stem was also shortened 8 mm (Figs. II-7 and II-8).

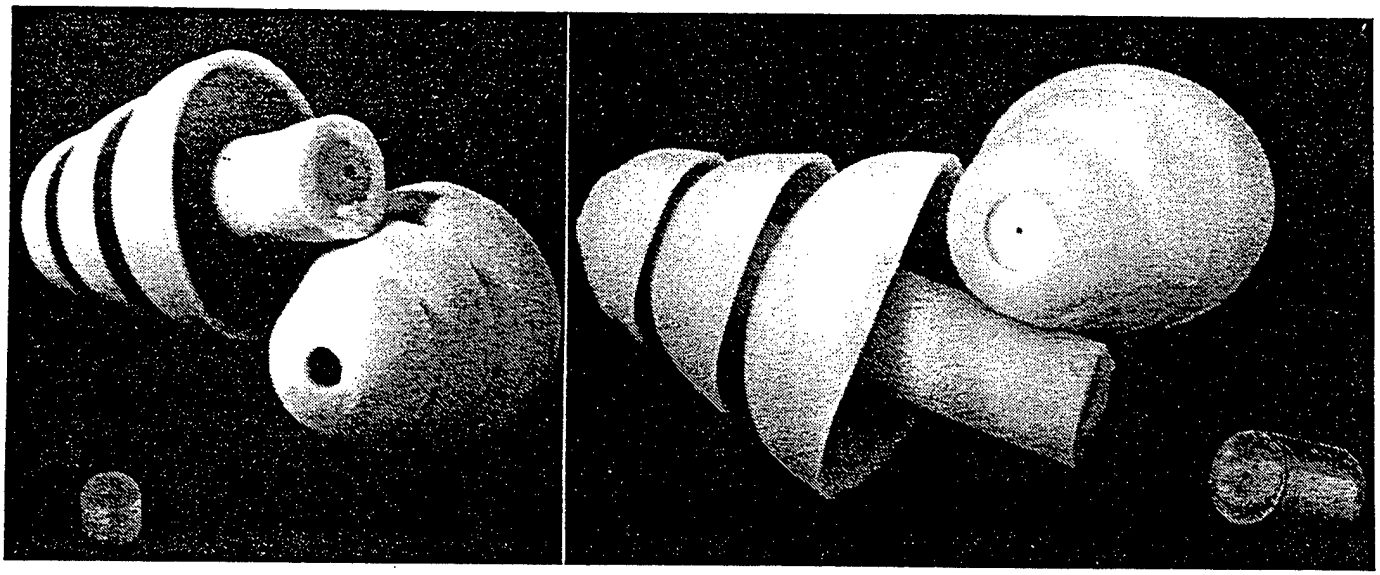
4. French No. 1 Plug

This plug is also a modification of the triple-flange E.A.R.® ultrafit with a 2-mm diameter hole through its longitudinal axis. The modification consisted of shortening the stem by 8 mm and putting the filter designed at ISL, St. Louis, France, in the front end of the plug (see Fig. II-7). A detail of the filter is shown in Figure II-9.

5. E.A.R.® Foam Plug

This is the standard plug sold by E.A.R.® (see Fig.II-7).

Figure II-6. The RACAL® Muff (Upper) and the RACAL® Muff Modified with Eight Tubes Through the Right Seal (Lower).



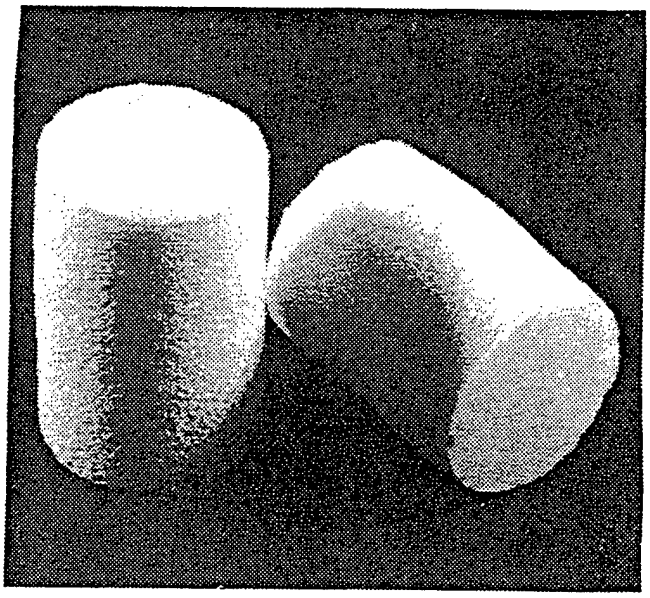


Figure II-7.The Rucker Plug (Upper Left) the French No. 1 Plug (Upper Right), and the E.A.R.® Foam Plug (Lower).

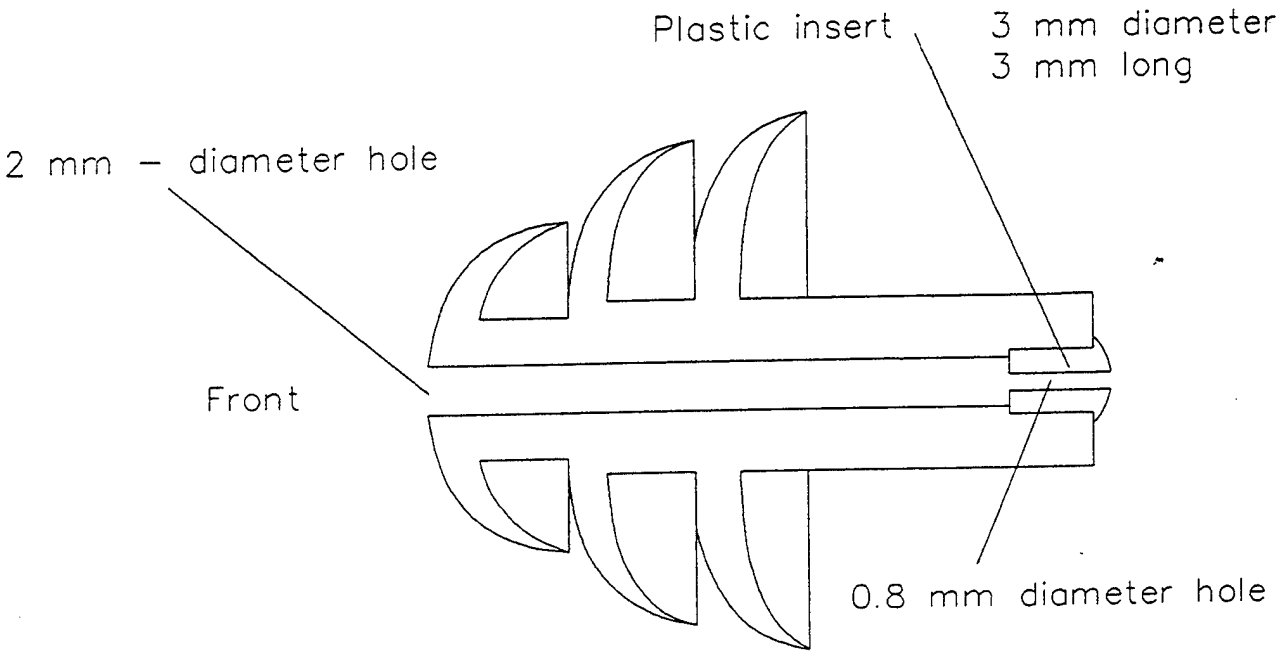


Figure II-8. Details of Rucker-Designed Plug and Filter.

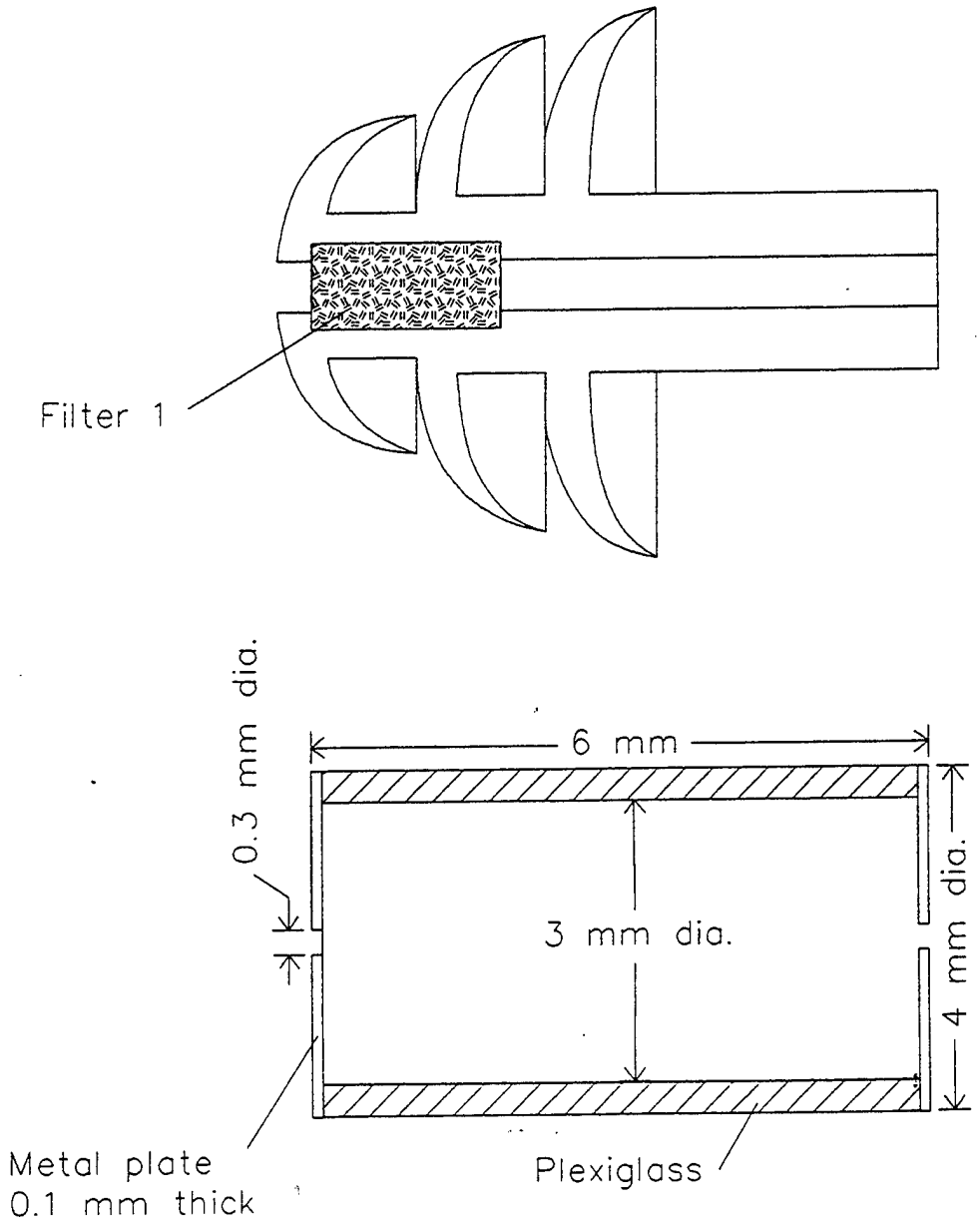


Figure II-9. Details of the ISL-Designed (French No. 1) Plug and Filter.

III. RESULTS

A. FIRING FROM A BUNKER SIMULATOR STUDY

1. Overview

Testing was started in July 1994 and ended May 1995. Sixty-four subjects started the exposure sequence and 59 subjects finished. Three subjects elected to quit before the end of the study and two subjects were administratively stopped for medical reasons. These conditions were not considered blast related, but were due to preexisting conditions (see Medical Data Section).

2. Attenuation of Hearing Protectors Tested

The baseline physical ear attenuation test (PEAT) values for the modified RACAL® muff are shown in Table III-1. The baseline was established by using the mean of at least eight tests. These tests were screened for obvious errors, fitting problems, or tests that were not consistent with most of the tests. The mean data are from 64 subjects. The standard deviation of the mean was calculated from the mean baseline value of each subject.

3. Auditory

a. Summary of Auditory Failures

For the 64 subjects that started the study, there were no full auditory failures (TTS >25 dB). There was only a conditional auditory failure (TTS 25 dB >TTS >15 dB). The summary of this conditional failure is shown in Table III-2.

Table III-1

Mean Attenuation Values for the
Modified RACAL® Muff (Right Ear, Modified Muff Only)
Using PEAT Baseline Values for 64 Subjects

Frequency (Hz)	Left Ear		Right Ear	
	Mean (dB)	Std. Dev	Mean (dB)	Std. Dev
125	5.83	5.73	-2.28	1.75
160	8.38	5.36	-3.73	2.51
200	9.69	5.65	-4.46	2.85
250	8.78	7.42	-4.85	2.78
315	12.65	7.70	-3.74	3.39
400	14.69	8.45	0.16	4.08
500	20.47	10.76	9.08	4.48
630	23.29	10.26	12.27	4.06
800	24.91	9.17	14.12	3.67
1000	25.28	9.37	17.63	3.75
1250	24.03	7.33	18.97	3.71
1600	26.55	7.06	22.60	3.40
2000	27.41	5.60	26.19	3.46
2500	29.62	5.22	29.55	4.14
3150	32.22	5.89	31.27	5.14
4000	33.95	5.81	31.08	5.62
5000	31.28	5.61	25.27	5.20
6300	32.26	5.93	23.21	5.18
8000	32.38	6.19	21.77	5.47
10000	30.85	5.09	25.41	4.37

b. Matrix Status

Because of the lack of auditory failures the final matrix, Figure III-1, is quite simple. There were no full auditory failures against any of the cells of the matrix.

c. Mean TTS vs. Exposure Condition

While there was not a major shift in the hearing threshold level of any subject, the following analysis was done to see if there was any statistically significant effect with the change in the peak level of the exposure and to see if there was any effect with the increase of the total energy of the exposure. For this study distance, this approach is fully valid since none of the subjects were dropped because of an auditory failure.

Typical results of the linear regression of TTS's, exposure condition with increasing energy, are shown in Figure III-2. The frequency of 6 kHz was chosen as the regression with the greatest positive slope of the frequencies from 1 kHz to 8 kHz. A summary of the slopes at all frequencies of 1 kHz and higher is given in Table III-3. For comparison, the results from tests covering the previous five years are also included in Table III-3.

For the Firing from a Bunker Simulator Study, note that the slopes for all but 6 kHz are negative implying improved hearing with increasing exposure level. This is probably the result of a small learning effect.

Table III-2

Conditional Failure
Firing from a Bunker Simulator

Subject	Condition	TTS_2	TTS_{Max}	Frequency Hz	24-Hr Recovery	Cleared
1056	6/3	18	18	250	Yes	No

Table III-3

Slope of a Linear Regression vs. Intensity Level at Various Audiometric Frequencies for Firing from a Bunker Simulator and for Various Freefield Studies

Configuration	Ear	Frequency, kHz					
		1	2	3	4	6	8
5-meter "B"	Right	-0.1	-0.05	-0.11	-0.03	-0.06	-0.03
	Left	-0.17	-0.03	-0.07	-0.05	-0.08	0.01
5-meter "M"	Right	0.01	0.01	0.12	0.04	0.17	0.05
	Left	-0.18	0.01	0.04	0.03	0.06	-0.12
1-meter "D"	Right	0.02	0.09	0.08	0.11	0.17	0.04
	Left	0.08	-0.12	0.05	-0.06	-0.02	-0.02
3-meter "C"	Right	-0.25	0.09	0.12	0.39	0.38	0.48
	Left	-0.06	0.04	-0.06	0.02	0.08	0.02
3-meter "P"	Right	-0.14	0.62	0.56	0.05	0.69	0.94
	Left	0.06	0.26	-0.07	0.06	0.31	0.25
Firing from a Bunker Simulator	Right	-0.07	-0.14	-0.02	-0.08	0	-0.05

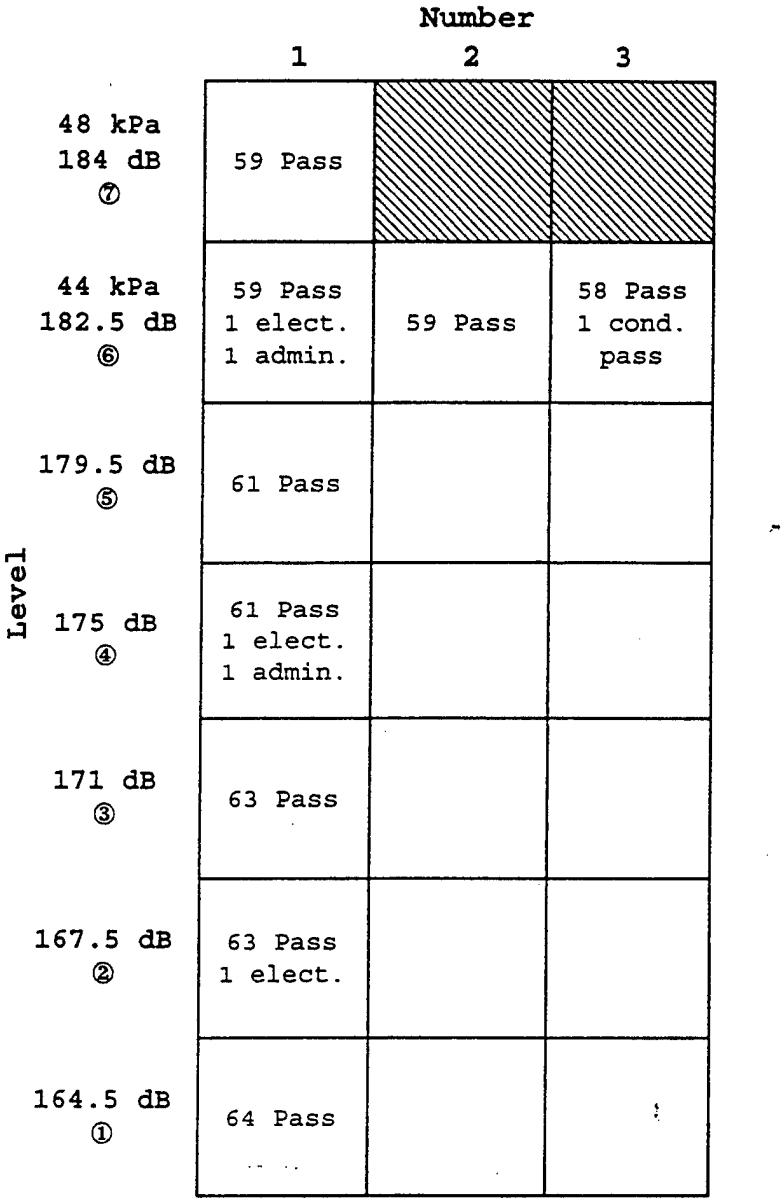


Figure III-1. Number of Subjects Passed and Number of Subjects Showing an Effect on Hearing at the Firing From a Bunker Simulator Study. The decibel levels are measured at the ear. The kPa levels are measured at the chest. "Elective refers to a subject's stopping by his own decision. "Admin." refers to a subject being dropped for some cause such as a chronic ulcer.

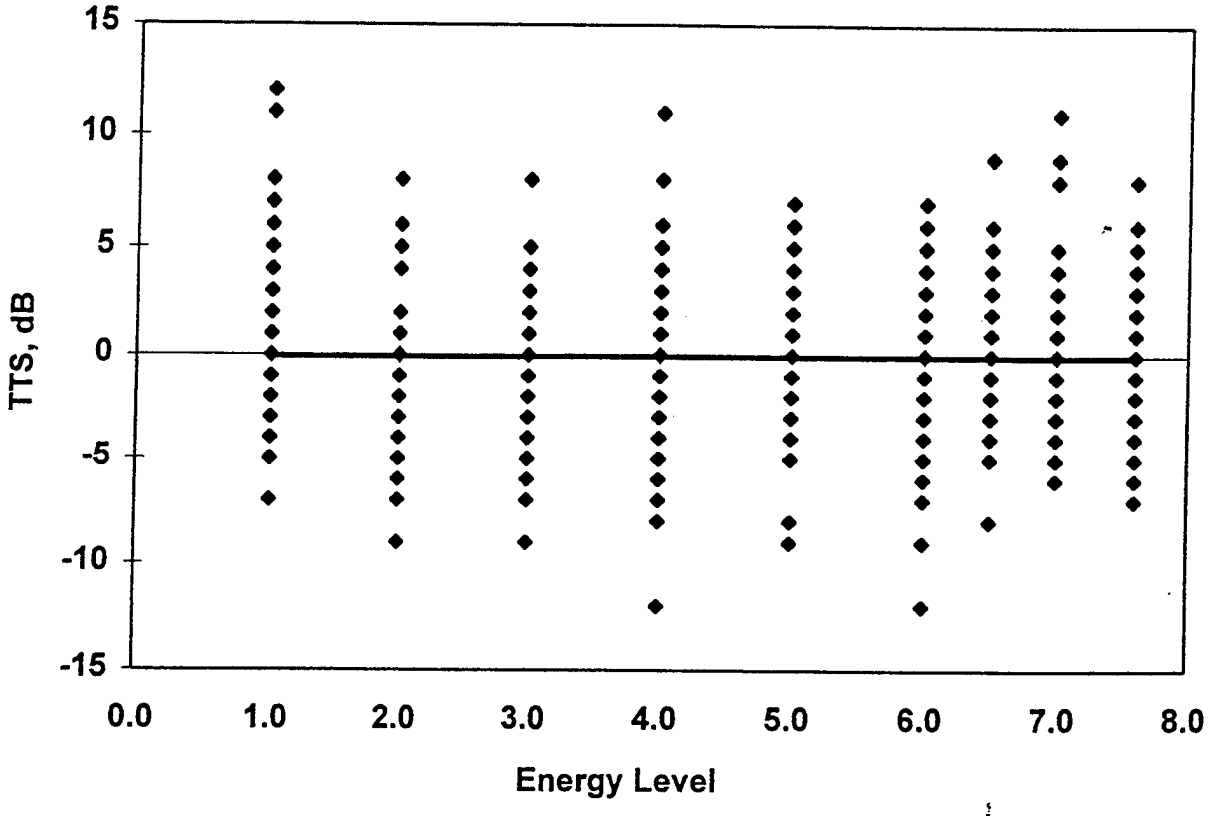


Figure III-2. Temporary Threshold Shift (TTS) in Hearing at 2-Minutes Post Exposure vs. Energy Levels. Each step is a doubling of level.

4. Nonauditory and Other

a. Nonauditory Injury

No nonauditory injuries occurred.

b. Acceptability Charts

(1). Questionnaire 1

The subjects who at least were exposed to Level 6 of the matrix were asked to provide an opinion as to the "acceptability to train" as they would individually define such a term. They were allowed to extrapolate for the conditions that they were not exposed. Figure III-3 is a summary of the results.

(2). Questionnaire 2

After the first questionnaire a second questionnaire was given to the subjects. This questionnaire provided a finer breakout. The questions and the responses to these questions are summarized in Figure III-4. The results of these questions basically followed the results of only using acceptable/nonacceptable.

(3). Rank Ordering of the Acceptability of Levels 2, 3, 4, 5, and 6 Compared to Levels 1 and 7

To obtain an indication of what the subjects thought about the various blast levels, a simple scale as to the acceptability of the different levels was used. The subjects were told of the task before the first exposure and were asked to fill in the form after Level 7 (Figure III-5). Information about what was meant by acceptability was not provided. In fact, the subjects were told that acceptability was up to them to define individually.

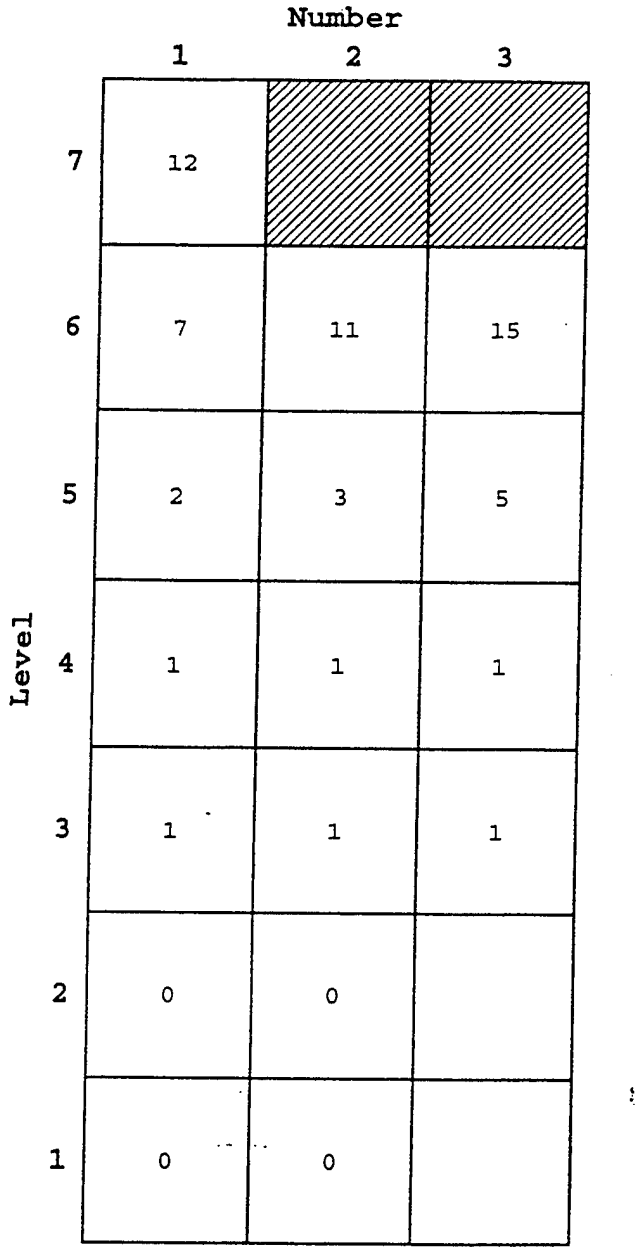


Figure III-3. Firing from a Bunker Simulator. Number out of 59 subjects that ranked the condition as unacceptable.

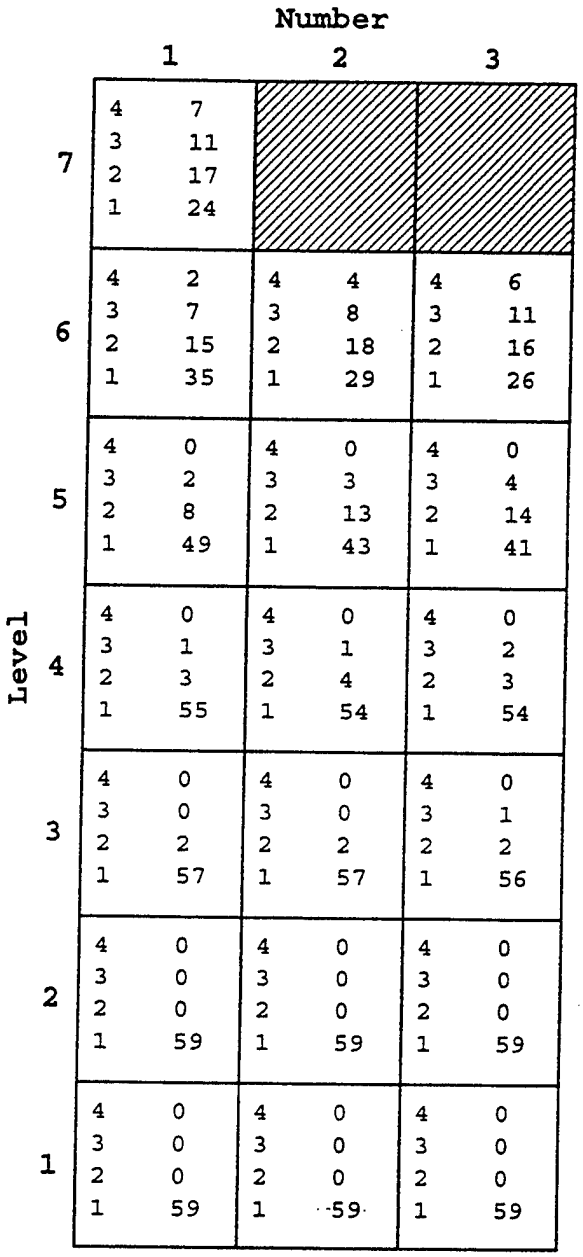


Figure III-4. Summary of 59 Subjects That Ranked Acceptability of Exposures per the Following:

1. Acceptable
2. Acceptable but would not look forward to day in which exposure occurred.
3. Marginally acceptable but would be concerned each time I was exposed.
4. Unacceptable

RANK ORDER																														
①		②			③					④						⑤										⑥			⑦	
01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Please rank order the acceptability of Levels 2, 3, 4, 5, and 6 fitting them in between Levels 1 through 7.

Figure III-5. Final Ranking of Firing from a Bunker Simulator, 59 Subjects.

Only subjects exposed to all seven levels were given the form.

c. Elective Failures

Table III-4 summarizes the elective failures. For the most part, these failures were for personal reasons such as family problems.

Table III-4

Elective Failures, Firing from a Bunker Simulator

Subject	Elected Not to Go To Level 7	Condition Elected Not To Go To	Election Stopped Further Exposure
1035	NA	2/1	Yes
1042	NA	4/1	Yes
1155	NA	6/1	Yes

Note that, of the 59 subjects that completed the study, none elected not to go to Level 7.

d. Exit Questionnaire

The results of the exit questionnaire are shown in Table III-5.

Table III-5

Summary of Exit Questionnaires
Firing from a Bunker Simulator

A. Introduction

The purpose of this questionnaire is to find out what you thought about the study and your part in it. The information you and others give concerning various aspects of the study will be used to 1) identify any problem areas which are in need of improvement, and 2) help monitor performance over the course of the study. Since there are some good and some bad aspects about being a part of this study, it is important to learn more about them. Asking you for your opinions is very important and it is the only way we can accomplish this task.

Question	Excellent	Good	Fair	Poor	No Answer
1. Information you received before you agreed to participate in this study.	10	35	11	3	0
2. How easy it was to get questions answered you might have had about being part of the study.	29	25	3	2	0
3. Accuracy of information provided to you when you were recruited concerning medical tests you would be subjected to.	25	24	9	1	0
4. Accuracy of the information provided when you were recruited regarding the effects on you of actual blasts.	28	25	5	1	0

Please read the following statements and state whether you agree or disagree with each statement. Think about the experiences you had while being a part of the study. When you cannot respond to a statement from your own experience, you can respond according to the experiences of other volunteers you know who were participants or you can write "uncertain". There are no right or wrong answers. We just want to know your opinions.

Question	Strongly Agree	Agree	Disagree	Strongly Disagree	No Answer
1. All of my questions were answered before I agreed to come to Albuquerque and be a part of this study.	14	36	9	0	0
2. I felt pressured into agreeing to participate in this study.	1	1	15	42	0

Table III-5 (Continued)

Question	Strongly Agree	Agree	Disagree	Strongly Disagree	No Answer
3. The laryngoscopic exams were uncomfortable and I would have preferred they had not been done.	13	19	20	4	3
4. The actual blast tests were more intense than I expected.	3	13	30	13	0
5. The physical discomfort I felt from the blasts was worse than I anticipated.	2	4	33	20	0
6. I was mentally bothered by the blasts.	1	0	22	36	0
7. Medical personnel always told me what to expect during examinations.	20	33	5	0	1
8. I need more break time between medical exams and tests.	0	3	41	15	0
9. My mental attitude was improved by participating in this study.	6	30	18	3	2
10. The medical personnel had plenty of time to do a good job.	16	41	2	0	0
11. I felt the military staff involved in the study were concerned about me personally.	24	29	6	0	0
12. My sleep pattern was disturbed during my participation in this study.	2	4	27	25	1
13. I'm glad I agreed to participate in this study.	34	22	2	0	1

Table III-5 (Continued)

Question	Strongly Agree	Agree	Disagree	Strongly Disagree	No Answer
14. I think my being a part of this study will benefit military personnel.	26	28	4	1	0
15. I would recommend to others that they agree to be a participant in this study.	26	31	1	0	1
16. The medical personnel treated me with care and concern.	33	25	1	0	0
17. Being a part of this study will benefit me later in life.	10	33	11	3	2

e. Medical Data

(1). General

A summary of the affirmative responses to the daily prexposure questionnaire is shown in Table III-6. There does not seem to be a trend toward more symptoms as the study progressed. Subject 1012 complained of stomach cramps before Level 5 and Subject 1182 had some intermittent stomach pain before Level 7. However, there was no rebound tenderness. The medical monitor did not consider any of these problems to be blast related. Two subjects were dropped because of medical reasons. One subject was found to have a chronic ulcer. This was discovered due to positive guaiac testing and verified through an examination. This subject was dropped from the study because the ulcer interfered with the purpose of the guaiac testing. Another subject reported a dizzy spell the evening of the day he had been exposed to Level 2. He was found to have a history of such spells and was dropped. The medical monitor did not consider the dizzy spell to be blast related.

Table III-6

Summary of the Responses on Daily Preexposure Medical Questionnaire for Firing from a Bunker Simulator Study vs. Exposure Level

ENERGY LEVEL	TOTAL COUNT	NOSE	MOUTH/ THROAT	EYES	SINUSES	EARS	CHEST	HEART	ABDOMEN
1	58	1	1	0	0	0	1	0	0
2	64	1	3	0	0	1	0	0	0
3	63	0	3	0	0	0	0	0	0
4	61	0	2	0	0	0	0	0	0
5	61	1	4	0	0	1	1	0	1
6	61	0	2	0	0	0	0	0	0
7	118	2	5	0	0	0	0	0	1
8	59	0	0	0	0	0	0	0	0

(2). Laryngoscopy

All examinations showed negative results, i.e., no petechiae on the larynx were found.

(3). Hemoguaiac Testing

Because of minor gastrointestinal (G.I.) tract injury in the sheep occurring above the threshold level (Yelverton et al., 1993), special attention was given to this testing. Figure III-6 shows the number of positive hemoguaiac test results compared with the total tests taken. Since a diet of raw fruits and red meat also can give positive results, we expected a positive preexposure rate was 5 percent. Therefore, since all post exposure positive hemoguaiac tests fell within the normal range of false positives, we do not believe that any G.I. tract injury was occurring in the subjects.

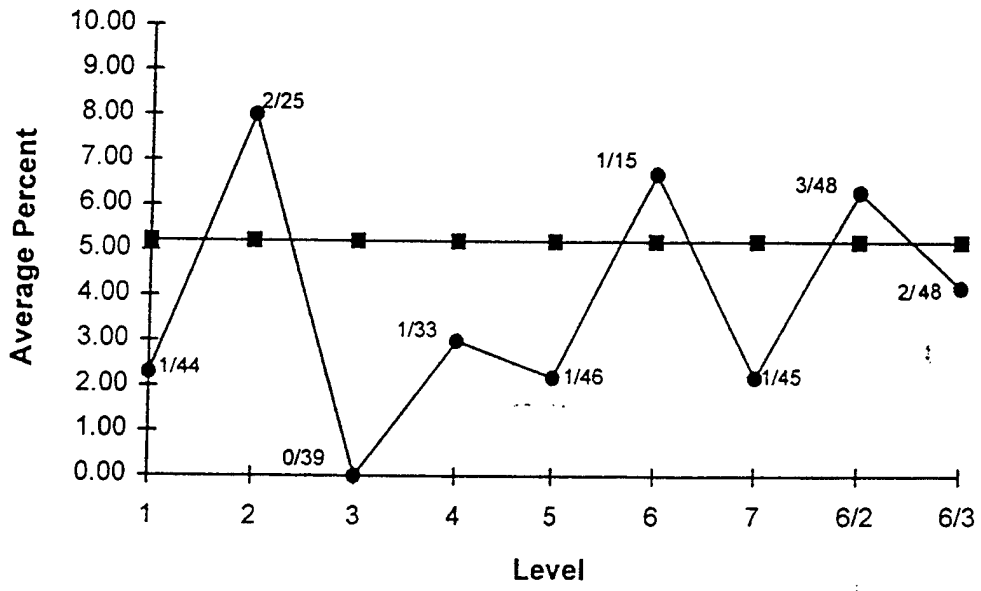


Figure III-6. Percent Hemoguaiac Tests that were Positive Out of Total Taken at Various Exposure Levels. A control level of 5 percent was the percent positive of the samples taken by all the subjects prior to the first exposure.

f. Performance Assessment Battery (PAB) Tests

The PAB scores for all the subjects are shown in Appendix J, Tables J1 and J2.

B. NONLINEAR EARPLUG STUDY

1. Overview of All Tests

The study was divided into two phases:

a. Phase 1

A nonlinear earplug (Rucker Plug, designed by the U.S. Army Aeromedical Research Laboratory (USAARL), Fort Rucker, AL.), was used on the subject's right (test) ear. The subject's left (nontest) ear was protected by an E.A.R.® foam plug. Thirteen subjects started and four subjects finished the study.

b. Phase 2

A nonlinear earplug (French No. 1 Plug, designed by the French-German Research Institute Saint-Louis (ISL), France), was used on the subject's right (test) ear. The subject's left (nontest) ear was protected by an E.A.R.® foam plug. Fourteen subjects started and four subjects finished the study.

2. Attenuation of Hearing Protectors

a. General

Since baselines using real ear attenuation (REAT) were made for all subjects, these data are presented. In addition, the insertion loss measurements done on the Rucker Plug by the personnel at the USAARL are given. Insertion loss measurements are defined as the difference in the measurements made with and without the protector placed in the ear canal of the artificial head. Likewise, ISL made similar measurements for the French No.1 Plug. The insertion loss measurements using the model at the ISL on their artificial head are given. In addition, the ISL artificial head became available to EG&G in September. The artificial head was placed on the pad and insertion loss data were taken for various plugs and muffs. Selected sets of these data are provided. The REAT measurements were also done. Comparison of these measurements is shown in Figure III-7.

b. Attenuation of the Rucker Plug

The average REAT attenuation of the Rucker Plug is shown in Table III-7. The results of the insertion loss tests done at Fort Rucker are shown in Figure III-8. These tests were accomplished with the KEMAR® artificial ear canal with a Piezotronics ST-2 gauge. A 6-inch diameter shock tube was used to simulate the impulse.

The ISL artificial head provided under-the-plug measurements for the actual waveform of the 3-m distance exposure. Selected waveforms are shown in Figures III-9. These can be compared with the freefield data of Appendix H (Fig. H-13). The 1/3-octave band analysis is shown in Figure III-10. The under-the-plug measurements are from a 190-dB peak impulse. Unfortunately, direct measurements using the ISL head without a plug could not be made because the microphone would saturate. An estimated spectrum, using a 173-dB peak impulse, is provided in Appendix H for comparison.

c. Attenuation of the French No. 1 Plug

The average REAT attenuation of the French No. 1 Plug is shown in Table III-8. The results of the insertion loss tests done at ISL with the ISL artificial head are shown in Figure III-11. As with the Rucker Plug, selected waveforms measured under the ISL head are shown in Figure III-12. The 1/3-octave band analysis is shown in Figure III-13.

d. Attenuation of the E.A.R.® Foam Plug

The REAT data for the left ear of all 27 subjects is shown in Table III-9. Insertion loss measurements of the E.A.R.® foam plug, using the 3-m blast wave, have been made with the ISL artificial head at 0-degrees and at 180-degrees to the direction of the blast wave. These measurements are shown in Figures III-14 and III-15. Note the difference between the measurements under the right ear (0-degrees to the blast) and the left ear (180-degrees to the blast so that the head shielded the ear from the blast) is about 6 dB for the peak measurement and 8 dB for the A-weighted energy and for the P-weighted energy. Thus, the shielding effect of the head with the E.A.R.® foam plug reduces the acoustical energy arriving at the eardrum by 8 dB. The difference between the 0-degree and 180-degree incidence for each 1/3-octave band is shown in Figure III-16. Note that the difference varies with frequency.

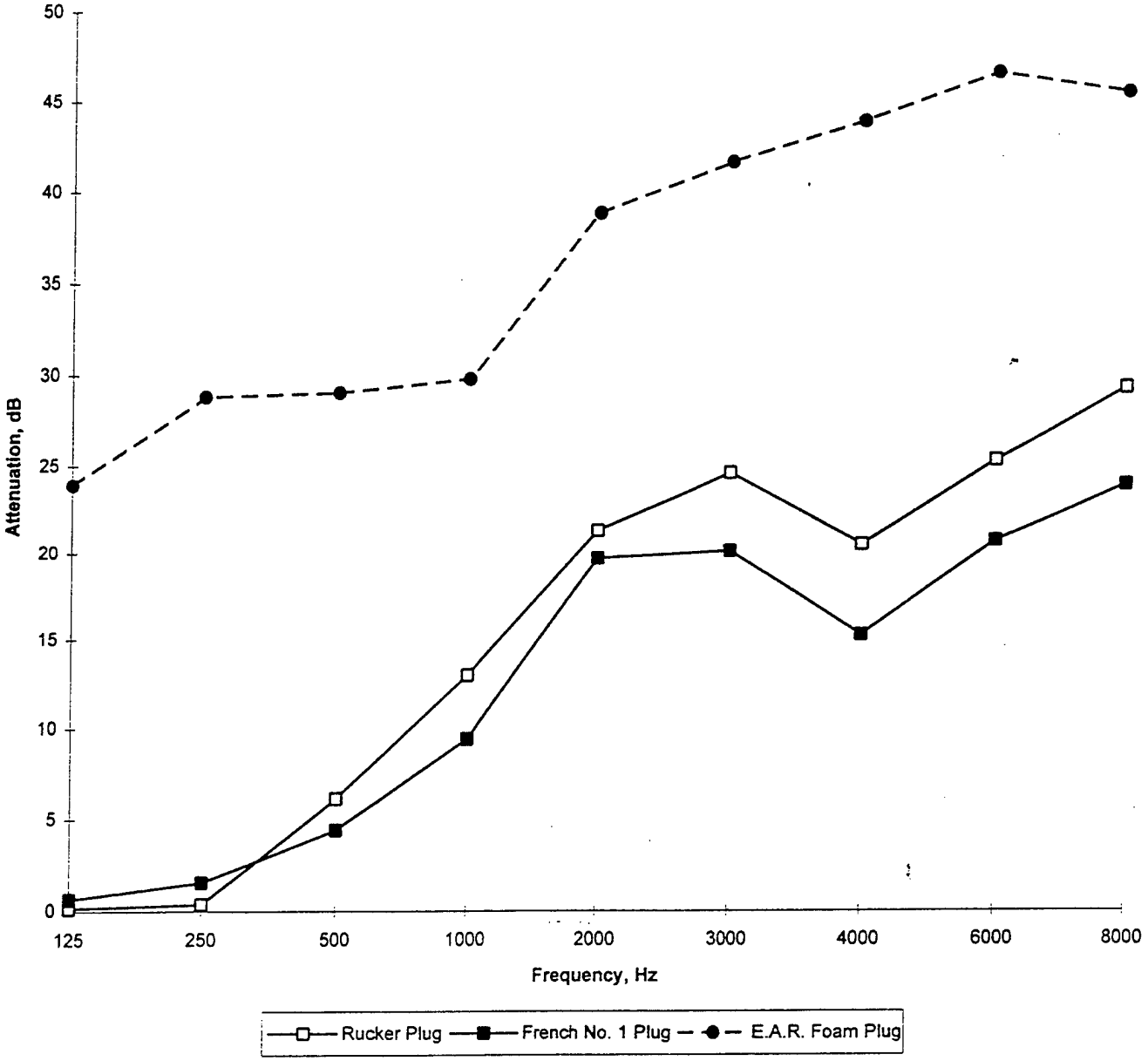


Figure III-7. Comparison of REAT Results for the Three Plugs Used in the Nonlinear Study.

Table III-7

Average REAT Attenuation, Rucker Plug

Frequency	125	250	500	1000	2000	3000	4000	6000	8000
Average	0.15	0.38	6.15	13.00	21.31	24.62	20.54	25.38	29.38
Std Dev	2.30	3.01	3.72	3.16	3.38	4.91	5.22	6.76	7.71

Table III-8

Average REAT Attenuation, French No. 1 Plug

Frequency	125	250	500	1000	2000	3000	4000	6000	8000
Average	0.64	1.57	4.43	9.43	19.71	20.14	15.29	20.79	24.00
Std Dev	2.21	3.08	3.11	5.04	6.47	3.68	3.45	7.60	8.53

Table III-9

Average REAT Attenuation, E.A.R.® Foam Plug

Frequency	250	500	1000	2000	3000	4000	6000	125	8000
Average	28.85	29.07	29.81	38.85	41.67	43.96	46.70	23.93	45.63
Std Dev	4.97	6.03	4.91	5.72	5.50	5.37	6.81	7.01	6.22

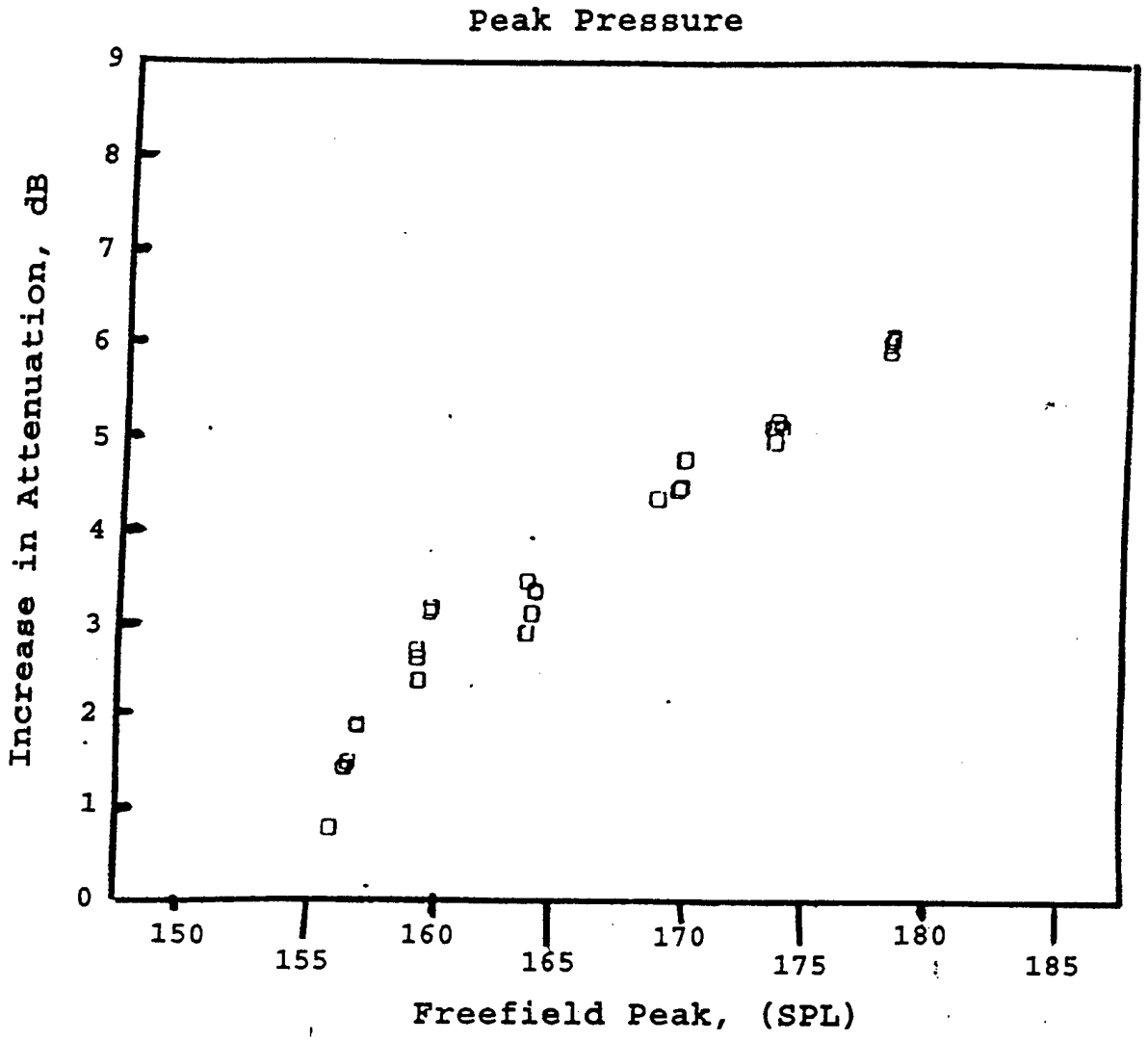


Figure III-8. Results of Insertion Loss Tests, Rucker Plug, Using a KEMAR® Artificial Ear Canal with a Piezotronic ST-2 Gauge.

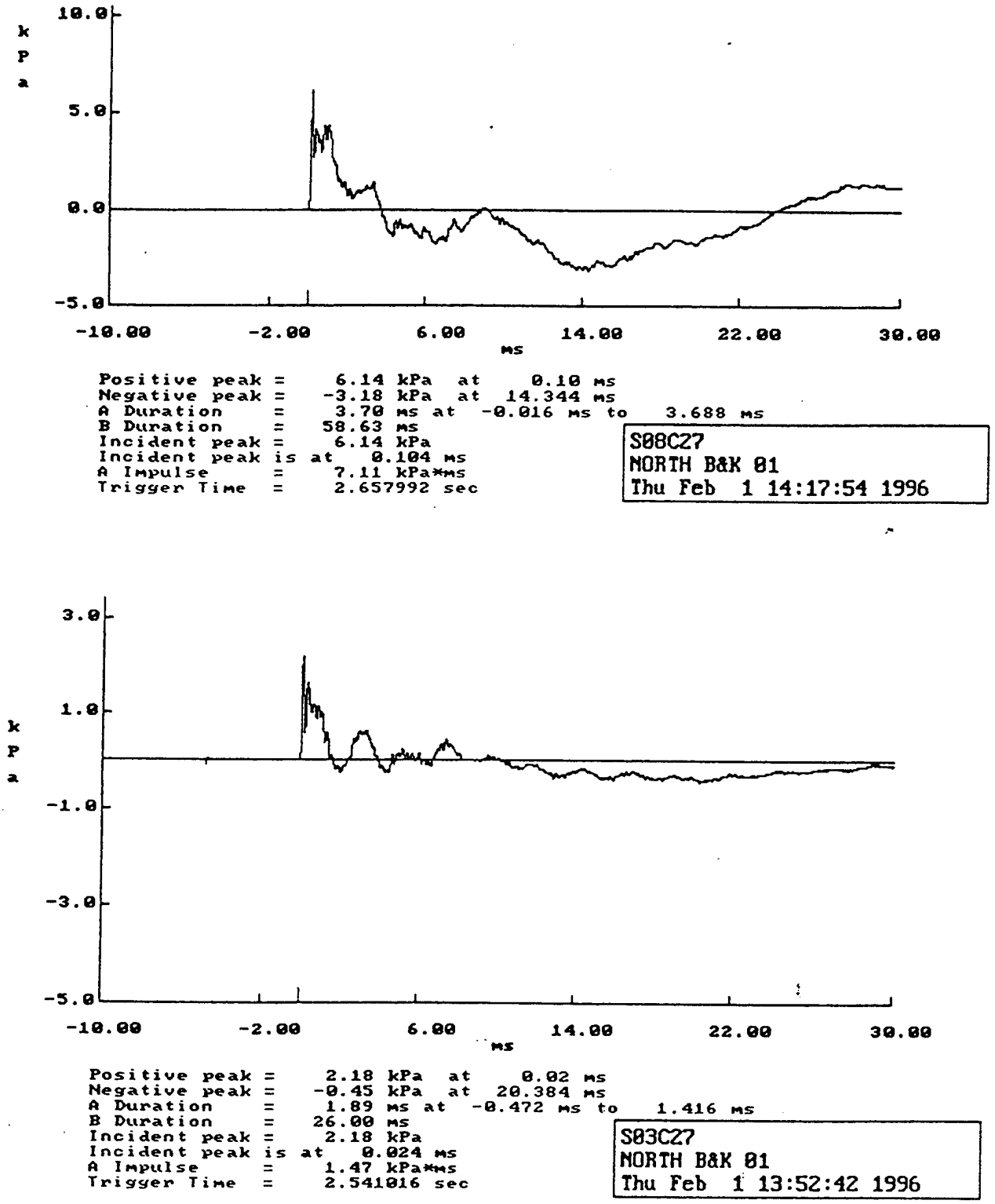


Figure III-9. Waveform Under-the-Plug Measurements, 3-m Distance, Rucker Plug, 190-dB Incident Peak, ISL Head. Top: Blast wave directly impinges on plug, 0-degree incidence. Bottom: Ear with plug shielded by the head, 180-degree incidence.

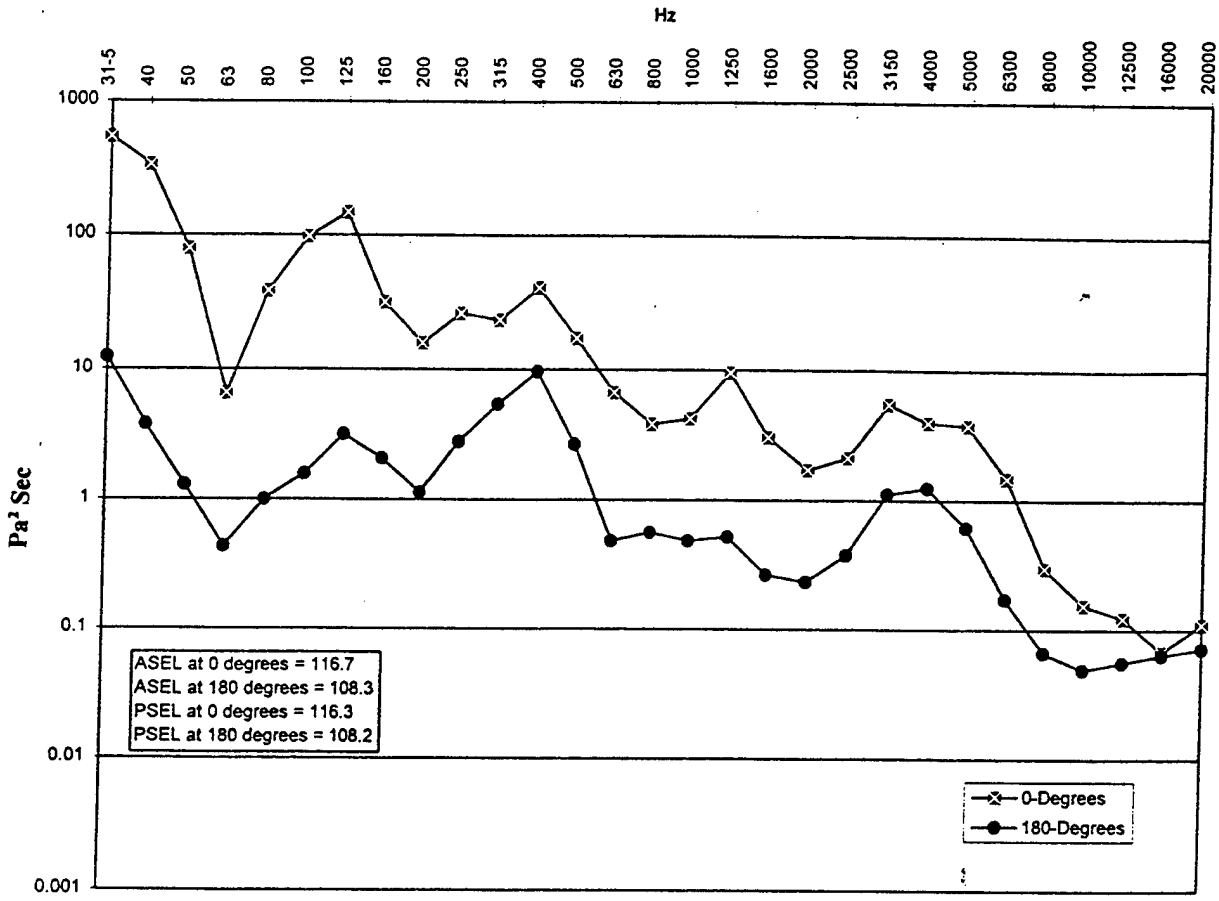


Figure III-10. 1/3-Octave Band Analysis Measured Under the Rucker Plug Using the ISL Artificial Head.

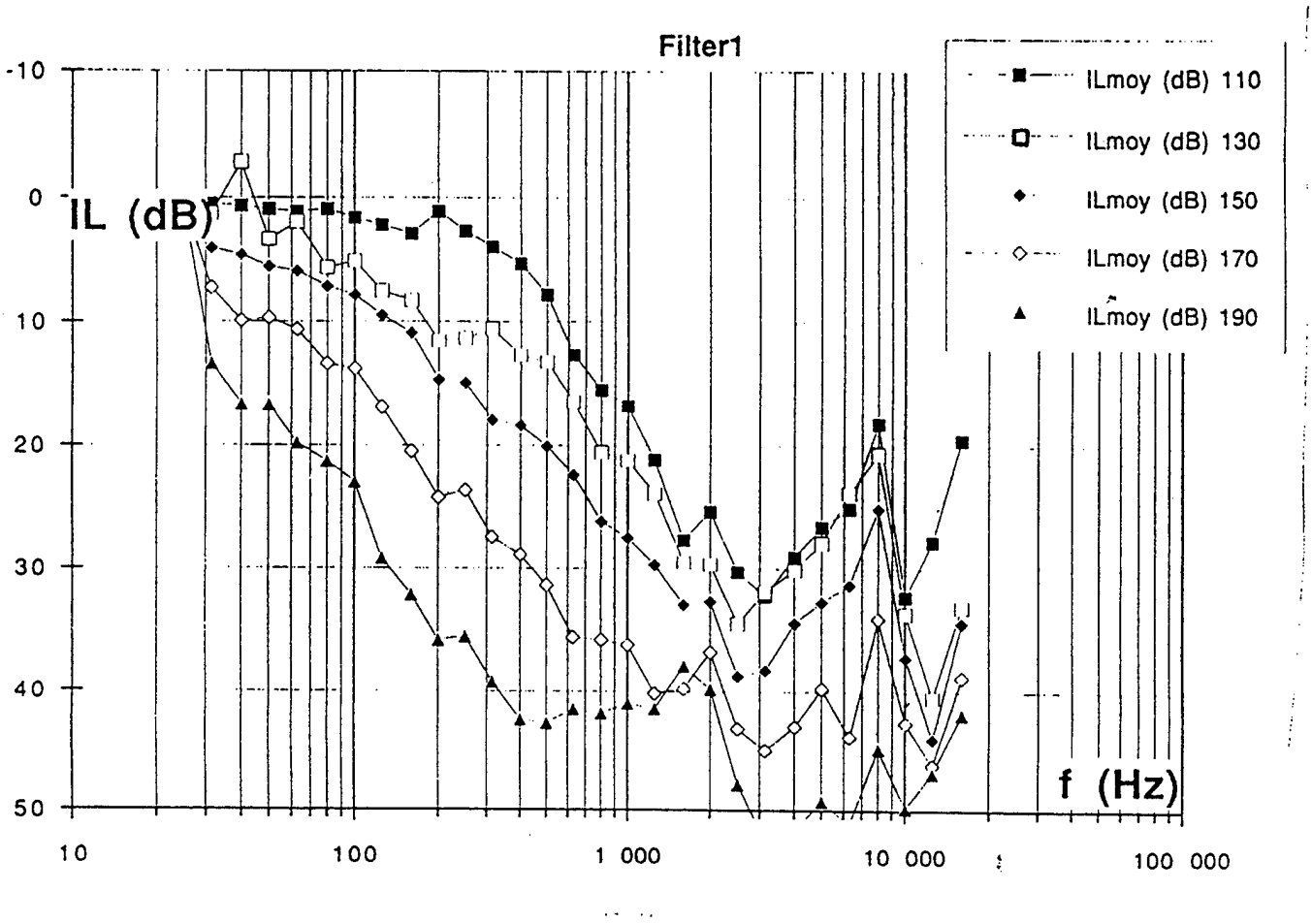


Figure III-11. Insertion Loss Tests Results at Different Peak SPL's, ISL Artificial Head.

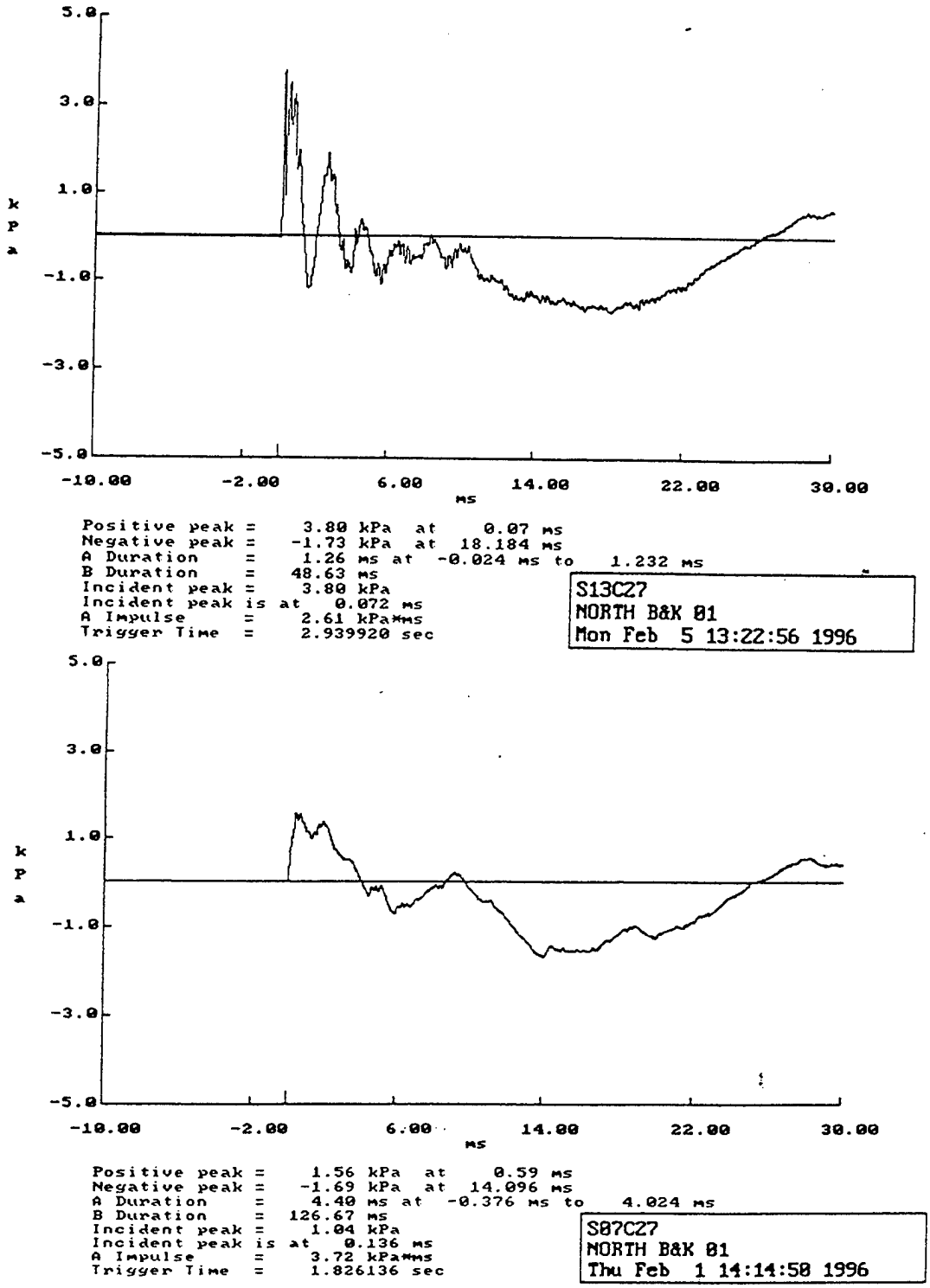


Figure III-12. Waveform Measured Under the French No. 1 Plug, 190 dB, 0-Degree Incidence, Upper; Waveform Measured Under the ISL Artificial Head, 180-Degree Incidence, Lower.

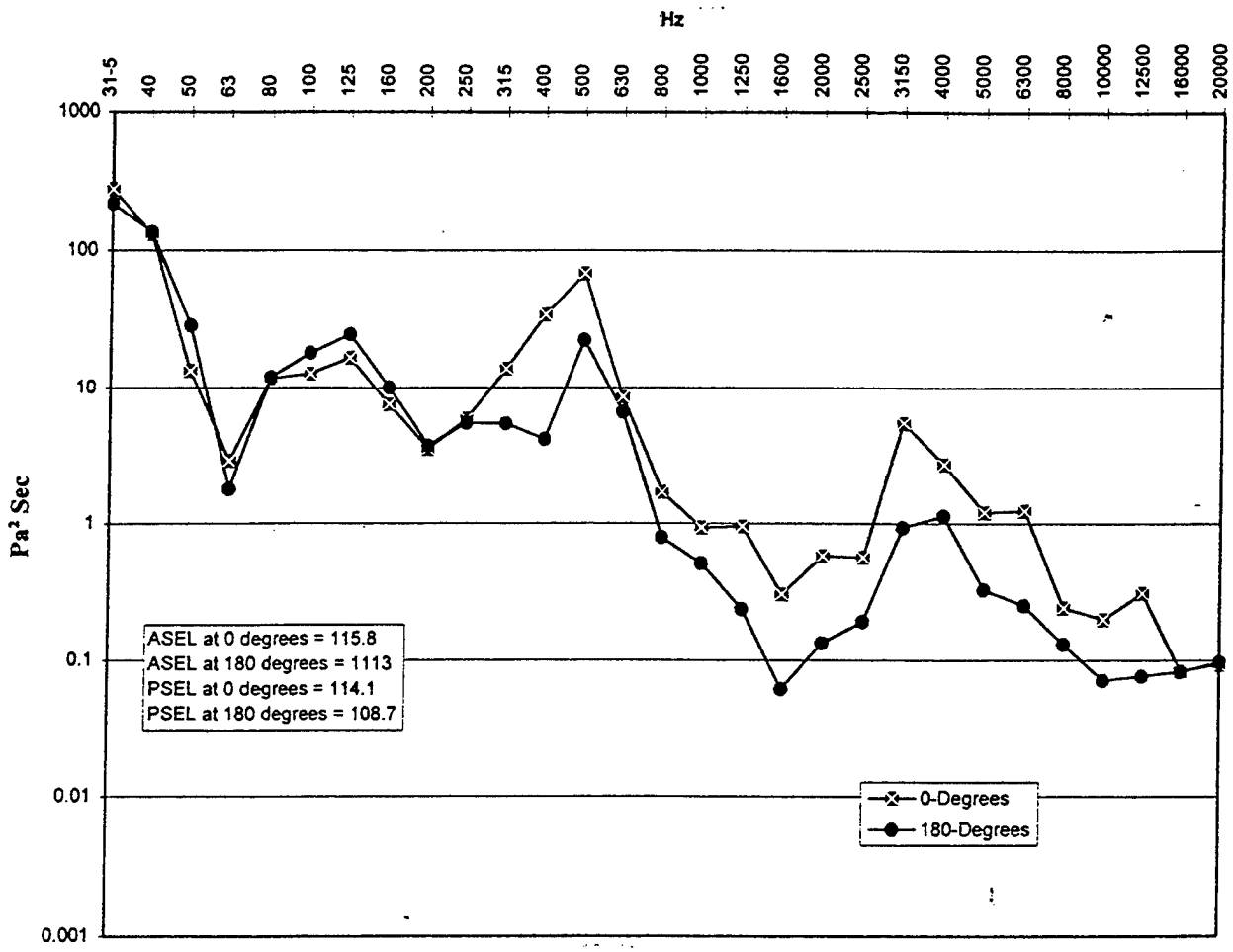
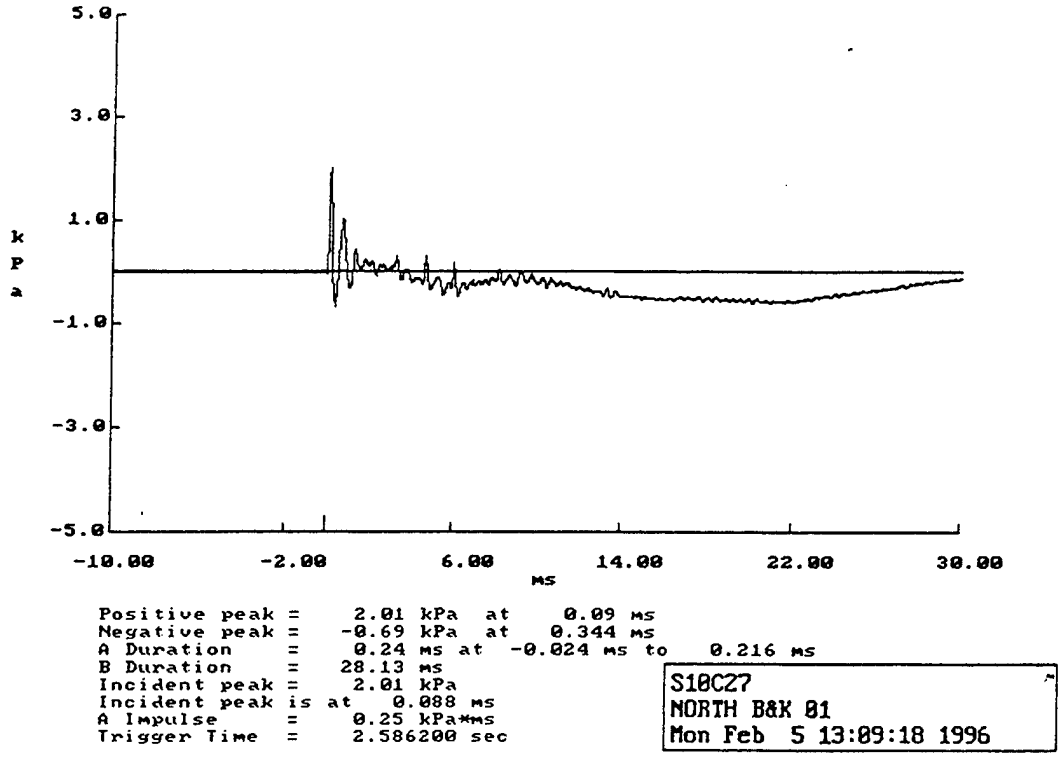


Figure III-13. 1/3-Octave Band Analysis Measured Under the French No. 1 Plug Using the ISL Artificial Head.



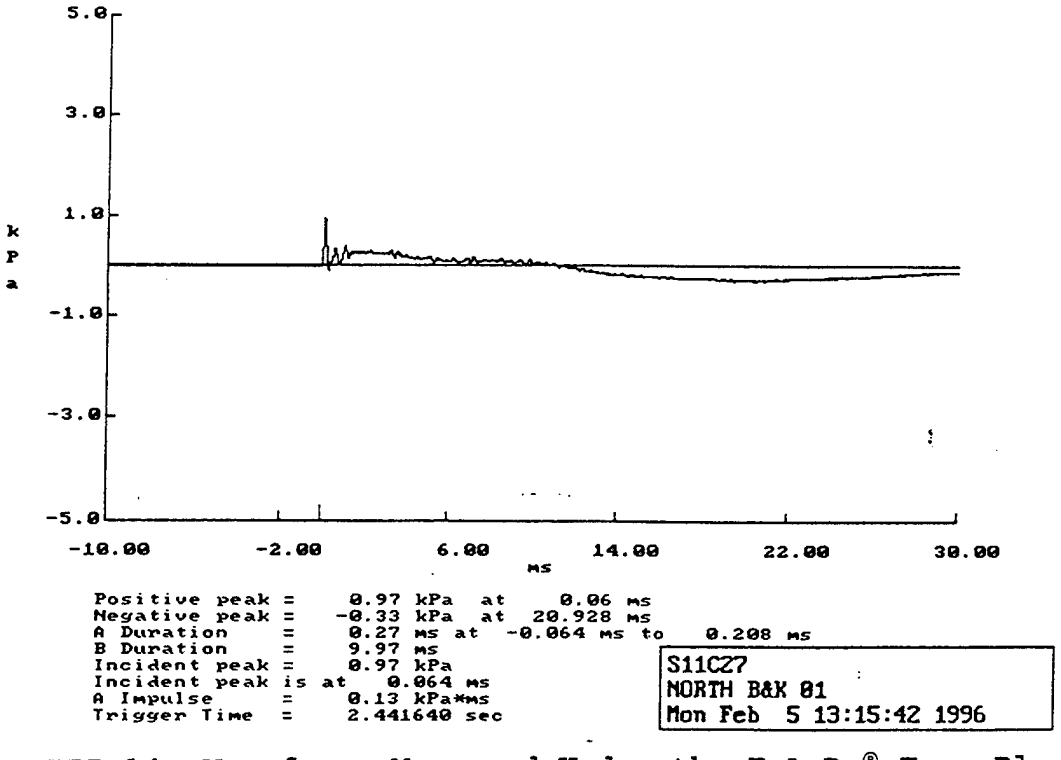


Figure III-14. Waveforms Measured Under the E.A.R.® Foam Plug, 3-m Distance, Using the ISL Artificial Head. Top: 0-degree incidence (ear facing the blast); bottom: 180-degree incidence (ear facing away from the blast).

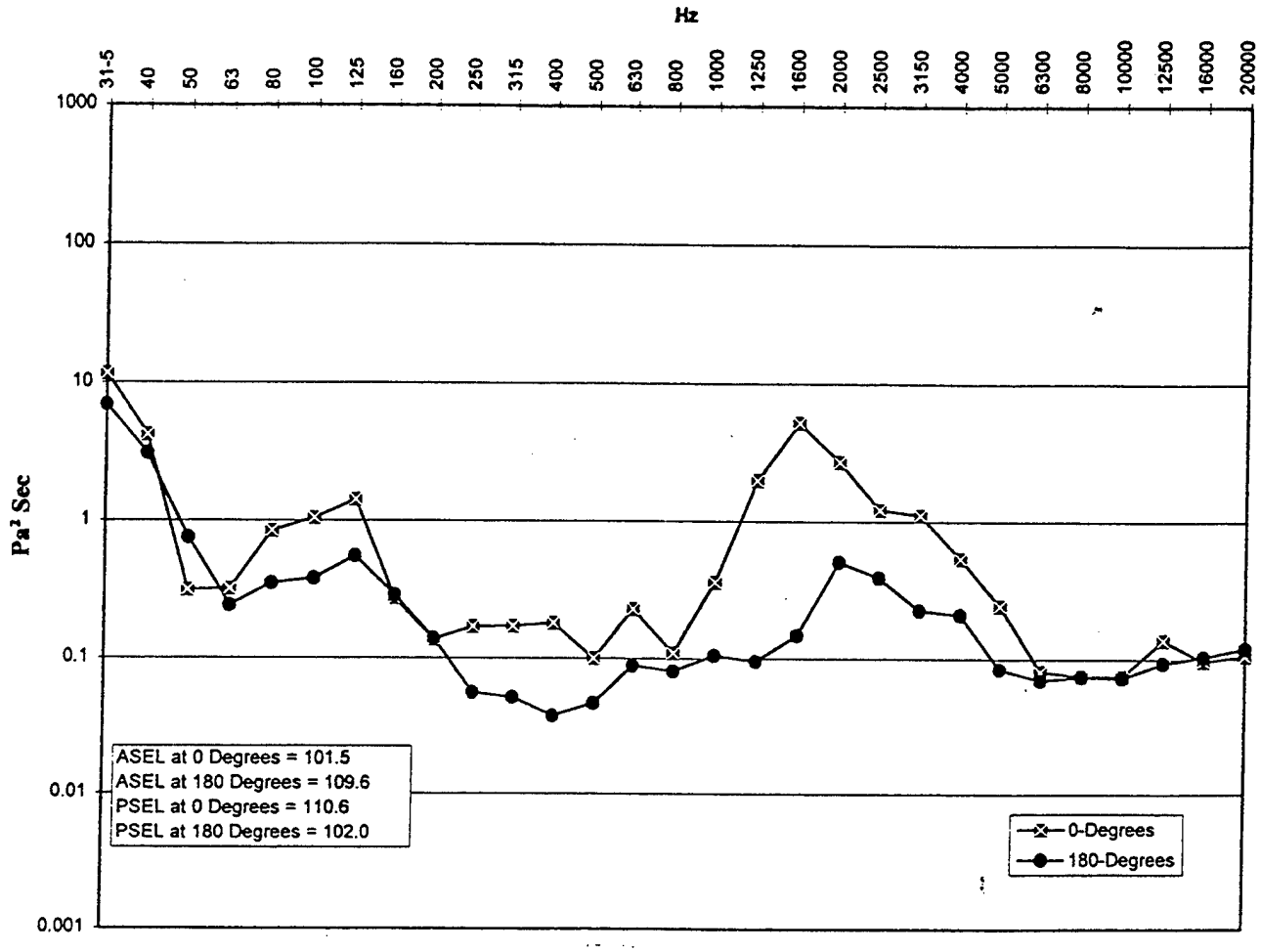


Figure III-15. 1/3-Octave Band Analysis Measured Under the E.A.R.® Foam Plug, 3-m Distance, Using the ISL Artificial Head.

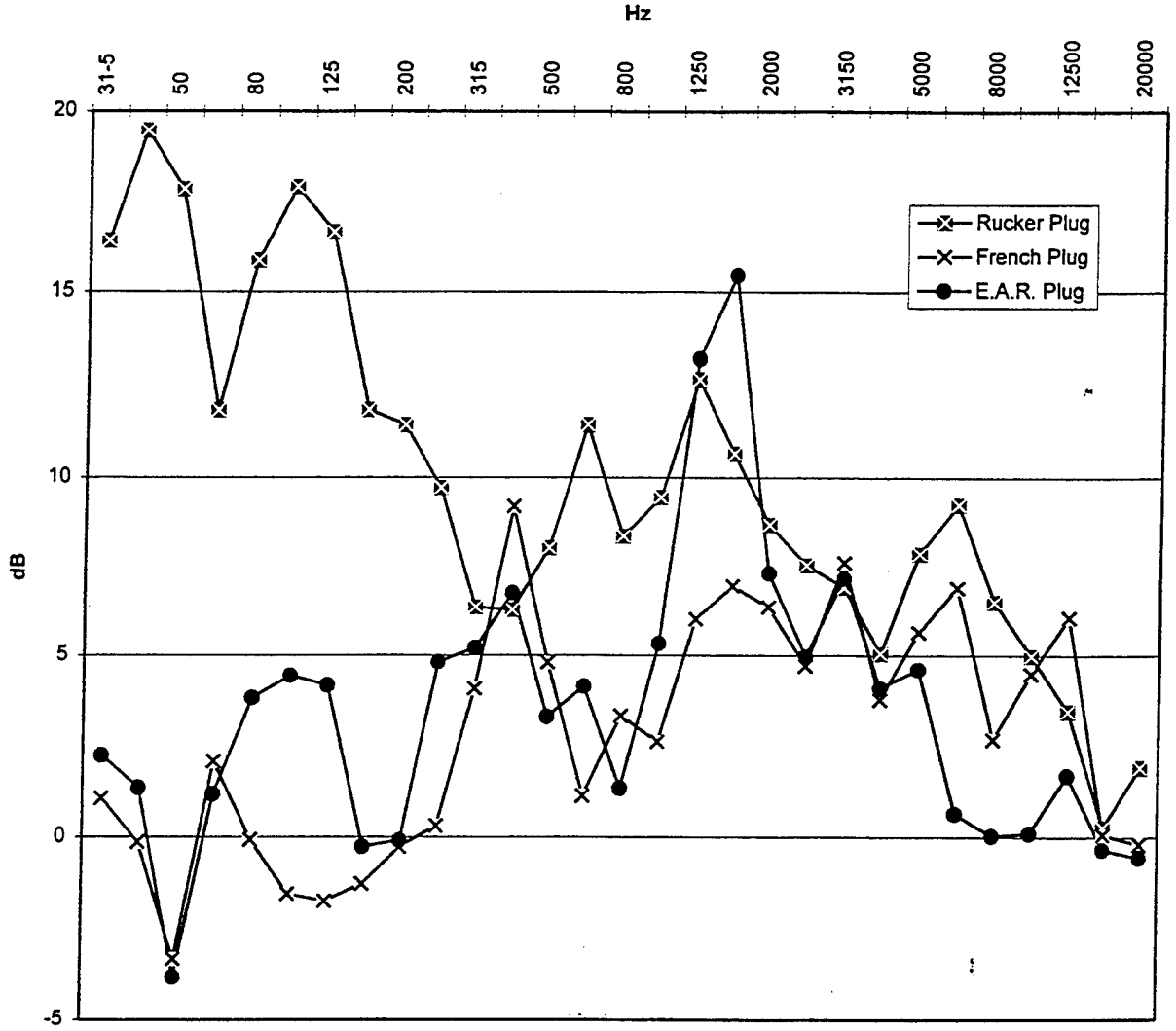


Figure III-16. Comparison of the Differences, in Decibels, Between 0-Degree Incidence and 180-Degree Incidence for Three Plugs Used in the Studies.

3. Auditory

a. Rucker Plug

(1). Summary of Auditory Failures

For the 13 subjects that started the study, there were four auditory failures and three conditional failures that were not cleared by the subject's passing a condition of the same level with more shots. The summary of these failures is as follows (Tables III-10 and III-11):

TABLE III-10

Summary of Conditional Failures
Rucker Plug

Subject	Condition	TTS_2, dB	TTS_{MAX}, dB	Frequency, kHz	Cleared
2022	6/50	17	17	2	No
2023	5/5	14	18 (20 min)	3	No
2023	5/12	22	22	3	No

TABLE III-11

Full Audiometric Failures
Rucker Plug

Subject	Condition	TTS_2, dB	TTS_{MAX}, dB	Frequency, kHz	24-Hr Recovery	Allowed To Continue
2016	3/6	20	39 (20 min)	2	Yes	Yes
2023	4/25	27	27	3	Yes	Yes
2025	3/6	0	25 (20 min)	1	Yes	Yes
2042	2/6	20 12	21 (20 min) 28 (1 hr)	2 1	Yes Yes	Yes Yes

(2). Matrix Status

The final status of the number of failures per matrix condition is shown in Figure III-17. A summary of subjects counted as failures at each condition is shown in Figure III-18. The percent of audiometric failures compared to the total number of subjects against that condition is shown in Figure III-19.

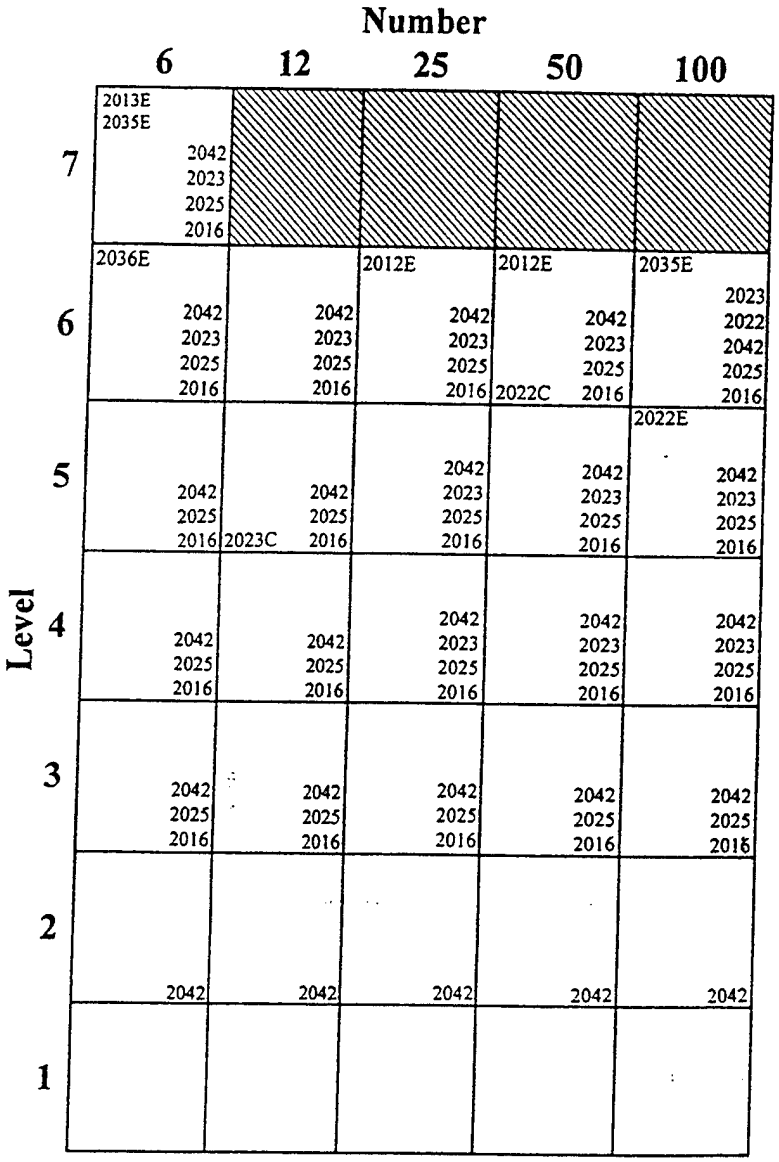


Figure III-17. List of Failures by Subject Number for Each Condition, Rucker Plug. (C = conditional failure; E = elective failure).

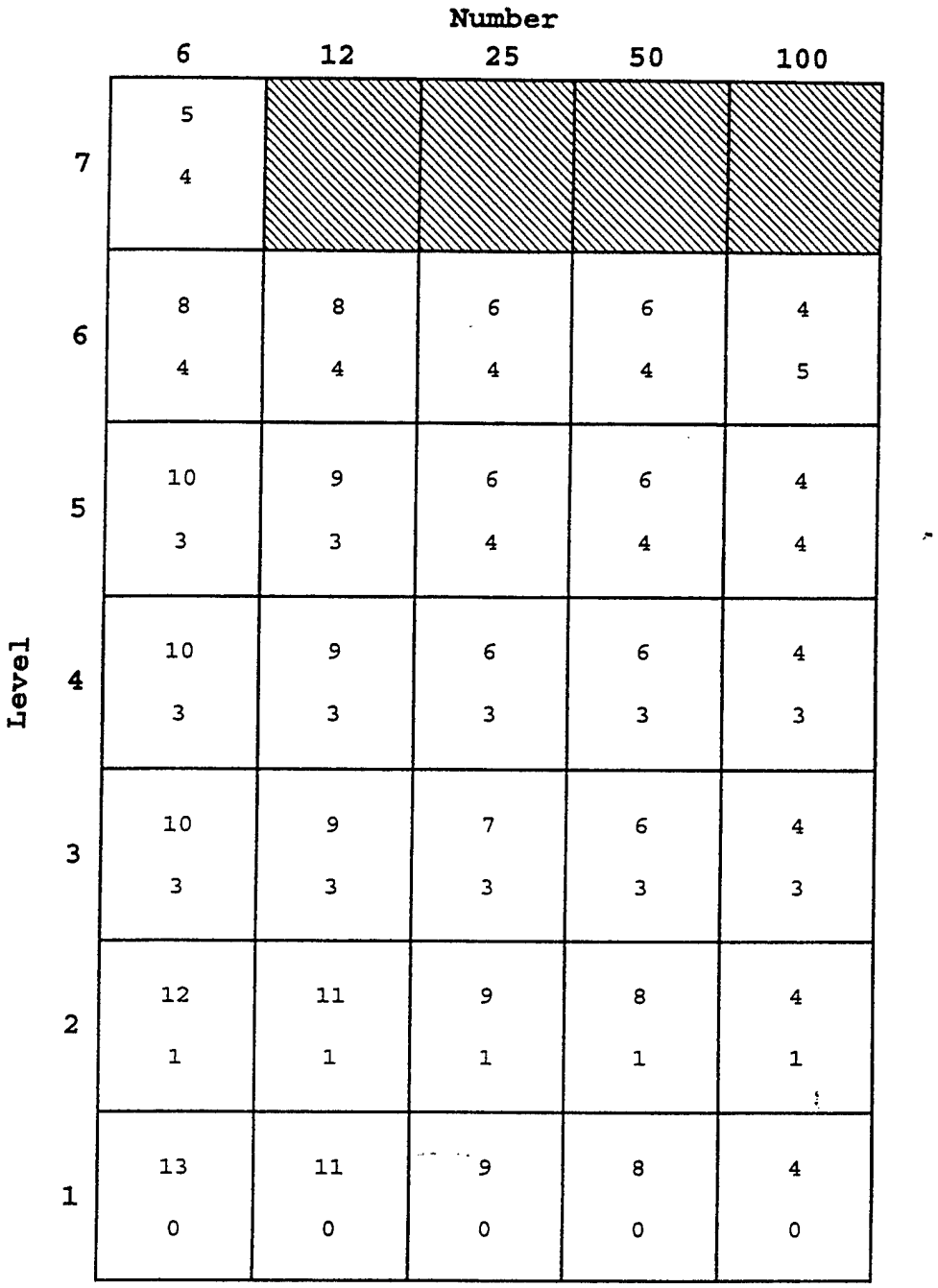


Figure III-18. Number of Individuals Passed (Top Number) and Number of Individuals Showing an Effect on Hearing (Bottom Number) for Each Condition. Rucker Plug, 3-m Distance, 13 Subjects.

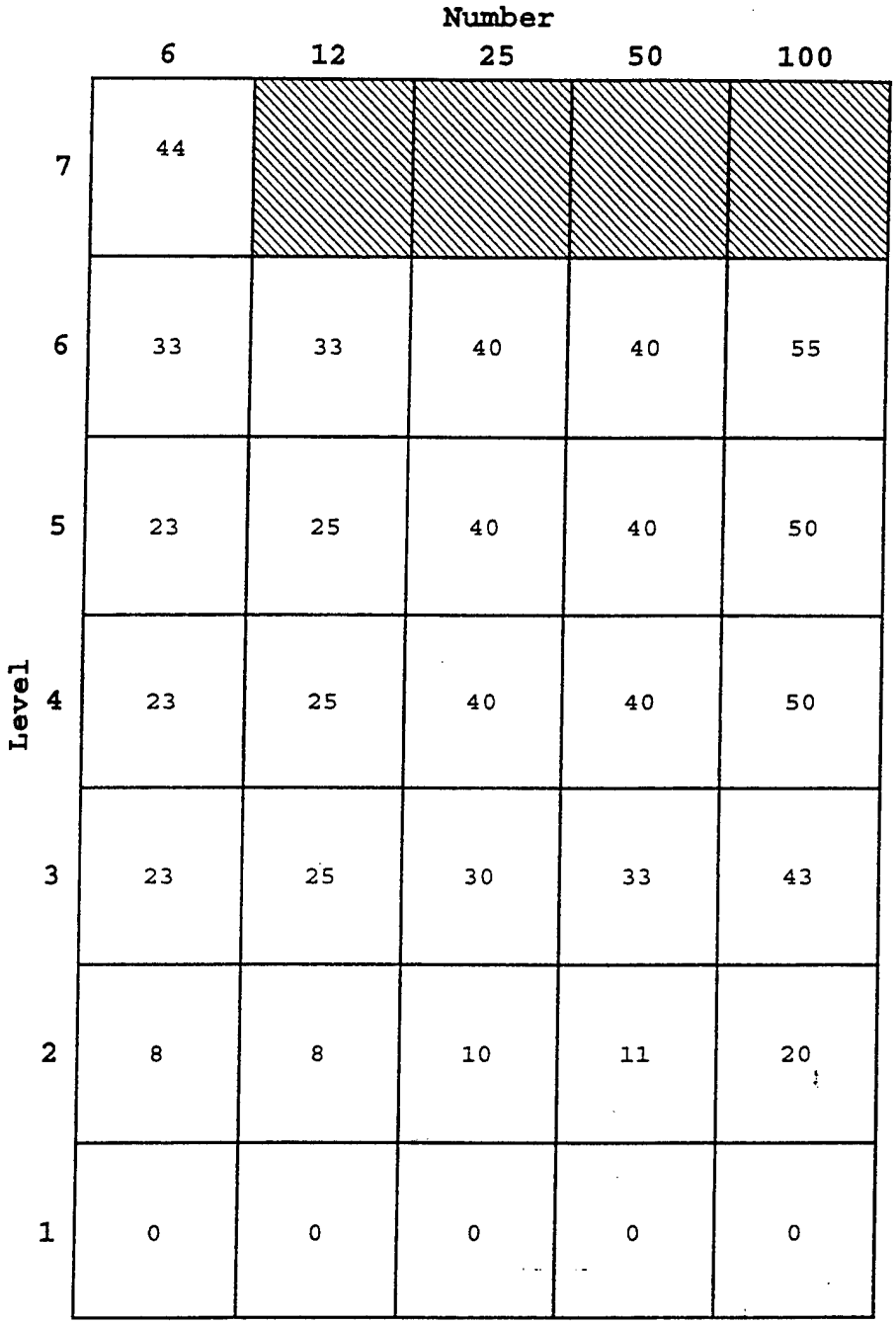


Figure III-19. Percent Audiometric Failures Compared to Total Number of Subjects that Either Passed Each Condition or Were Failures Against That Condition, Rucker Plug, 3-m Distance.

(3). Mean TTS vs. Exposure Energy

While there may not have been a major shift in the hearing threshold level of any subject, the following analysis was done to see if there was any statistically significant effect with the change in the peak level of the exposure as well as to see if there was any effect with the increase of the total energy of the exposure. The nature of the Walk-Up Study makes a normal regression analysis somewhat questionable because the more sensitive individuals are selected out before the high-exposure levels. With this caveat, the right ear data are presented for the Rucker Plug. The left ear data with the E.A.R.® foam plug will be covered later. The regressions are done by comparing TTS to energy levels. Energy Level 1 is the same as the exposure of 6 shots at Level 1. Energy Level 2 is either the exposure of 6 shots at Level 2 or 12 shots at Level 1. Thus, Energy Level 2 is 3 dB more than Energy Level 1. Energy Level 7 is, therefore, 6 shots at Level 7, 12 shots at Level 6, 25 shots at Level 5, etc.

The results of the linear regression of TTS vs. exposure energy is shown in Table III-12, a plot is shown for 6000 Hz in Figure III-20. The frequency of 6000 Hz was chosen as the regression with the greatest positive slope of the frequencies from 1 to 8 kHz.

Table III-12

Results of Linear Regression of TTS vs. Energy Level
Rucker Plug

Frequency, Hz	Slope	Y-Intercept	R	t Stat	Significance F
125	-0.01	-0.56	0.01	-0.07	0.94
250	-0.16	1.48	0.11	-1.16	0.25
500	-0.19	0.53	0.11	-1.12	0.27
1000	-0.15	1.65	0.08	-0.82	0.41
2000	-0.11	0.79	0.05	-0.56	0.58
3000	0.07	-0.74	0.03	0.32	0.75
4000	-0.04	0.04	0.02	-0.22	0.82
6000	0.09	-1.23	0.06	0.65	0.52
8000	0.03	-0.86	0.01	0.15	0.88

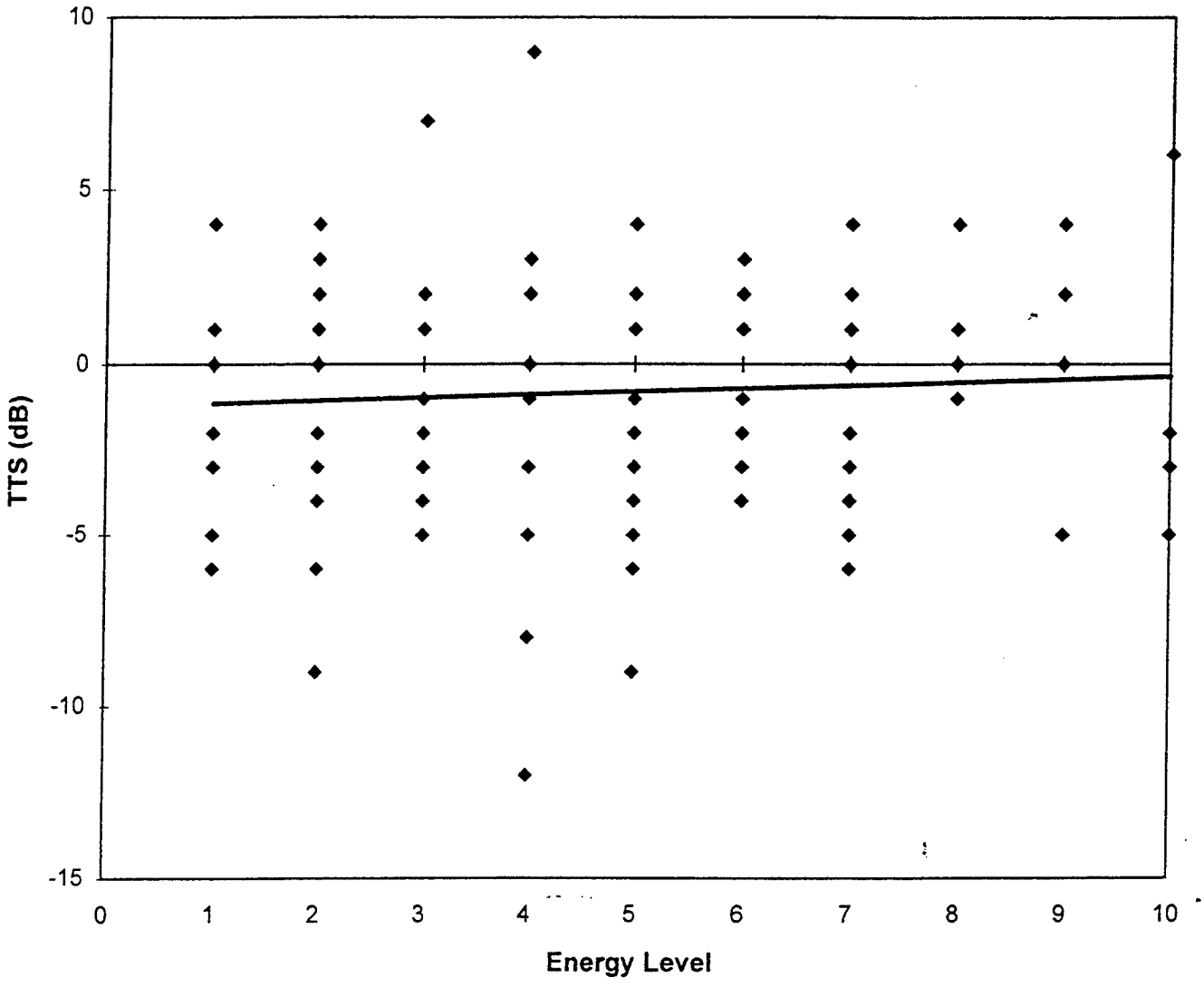


Figure III-20. Regression Analysis of TTS vs. Energy Level, 6000 Hz, Rucker Plug.

b. French No. 1 Plug

(1). Summary of Auditory Failures

For the 14 subjects that started the study, there were two full auditory failures and six conditional failures (five subjects) (Tables III-13 and III-14). Of the conditional failures, three were cleared by the subject passing the same level with more shots.

Table III-13

Conditional Failures
French No. 1 Plug

Subject	Condition	TTS_2, dB	TTS_{MAX}, dB	Frequency, kHz	Cleared
2055	1/6	16	16	2	Yes
2056	3/6	23	23	6	Yes
2065	6/50	19	22 (20 min)	4	No
2066	1/6	21	16	2	No
2066	1/12	16 13	16 17 (20 min)	2 3	No
2085	1/6	13	18	8	Yes

Table III-14

Full Audiometric Failures
French No. 1 Plug

Subject	Condition	TTS_2, dB	TTS_{MAX}, dB	Frequency, kHz	24-Hr Recovery	Allowed To Continue
2063	6/12	28	28	1	Yes	Yes
2076	3/12	25 15	38 (2 hr) 21 (20 min)	4 6	Yes	Yes

(2). Matrix Status

The final status of the number of failures per matrix condition is shown in Figure III-21. A summary of the number of subjects counted as failures versus the number of subjects counted as passes for each matrix condition is shown in Figure III-22. The percent of audiometric failures compared to the total number of subjects who either passed or failed the condition is shown in Figure III-23.

(3). Mean TTS vs. Exposure Energy

For the French No. 1 Plug, the same caveat applies as was stated for the Rucker Plug. Specifically, the more sensitive individuals are selected out before their TTS becomes too large. This selection process will reduce the slope of the possible growth of TTS.

Table III-15 provides the regression analysis for the French No. 1 Plug. Note that both 500 Hz and 1000 Hz show a significant effect. The significance at 1000 Hz is less than 0.01 significance, Figures III-24 and III-25.

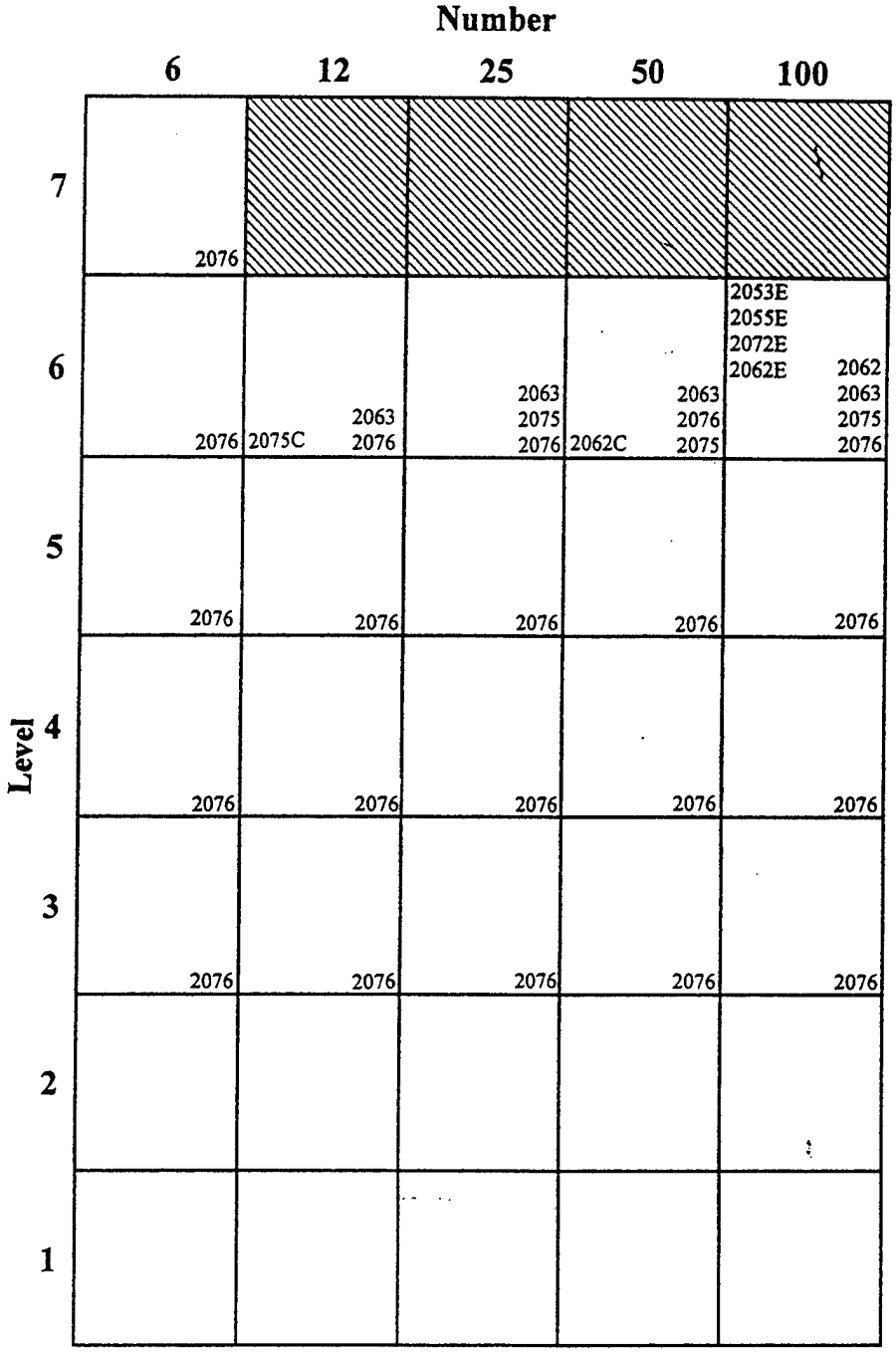


Figure III-21. List of Failures by Subject Number for Each Condition, French No. 1 Plug. Conditional failure of subject 2066 at Level 1 is not included because this subject could not be properly fitted with the French No. 1 plug. (C = conditional failure; E = elective failure).

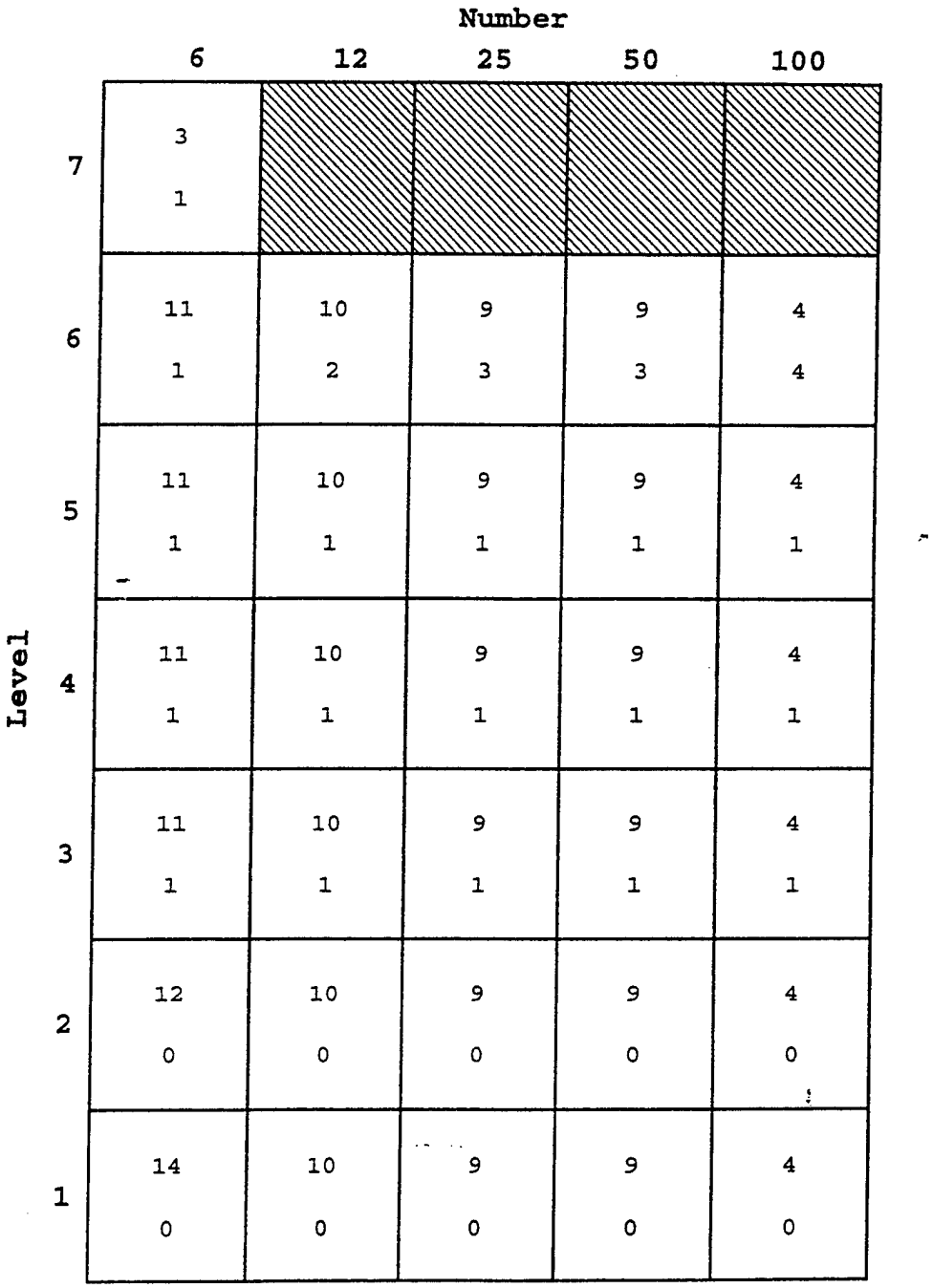


Figure III-22. Number of Individuals Passed (Top Number) and Number of Individuals Showing an Effect on Hearing (Bottom Number) for Each Condition for French No. 1 Plug, 3-m Distance, 14 Subjects.

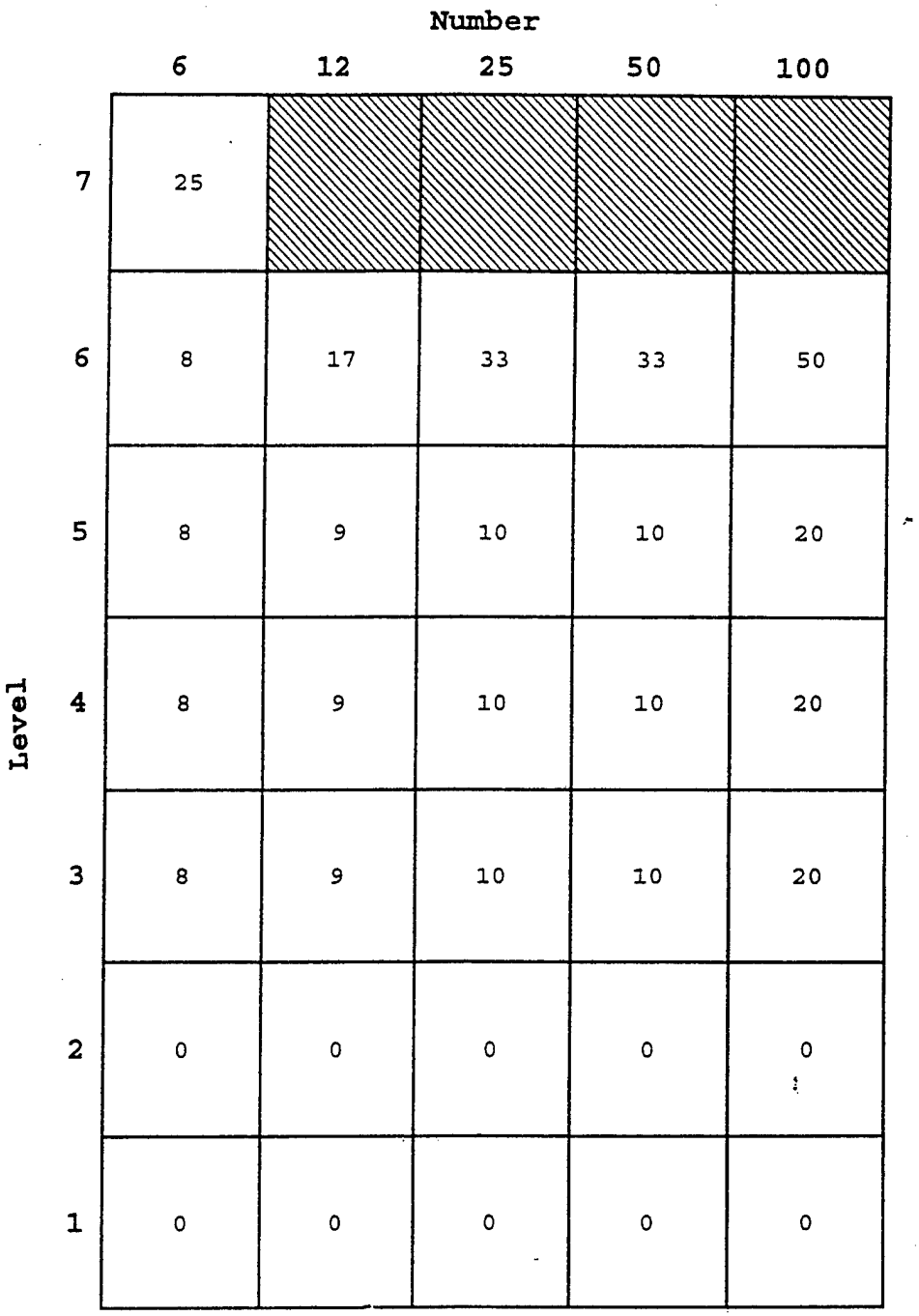


Figure III-23. Percent Audiometric Failures Compared to Total Number of Subjects that Either Passed Each Condition or Were Failures Against That Condition, French No. 1 Plug, 3-m Distance.

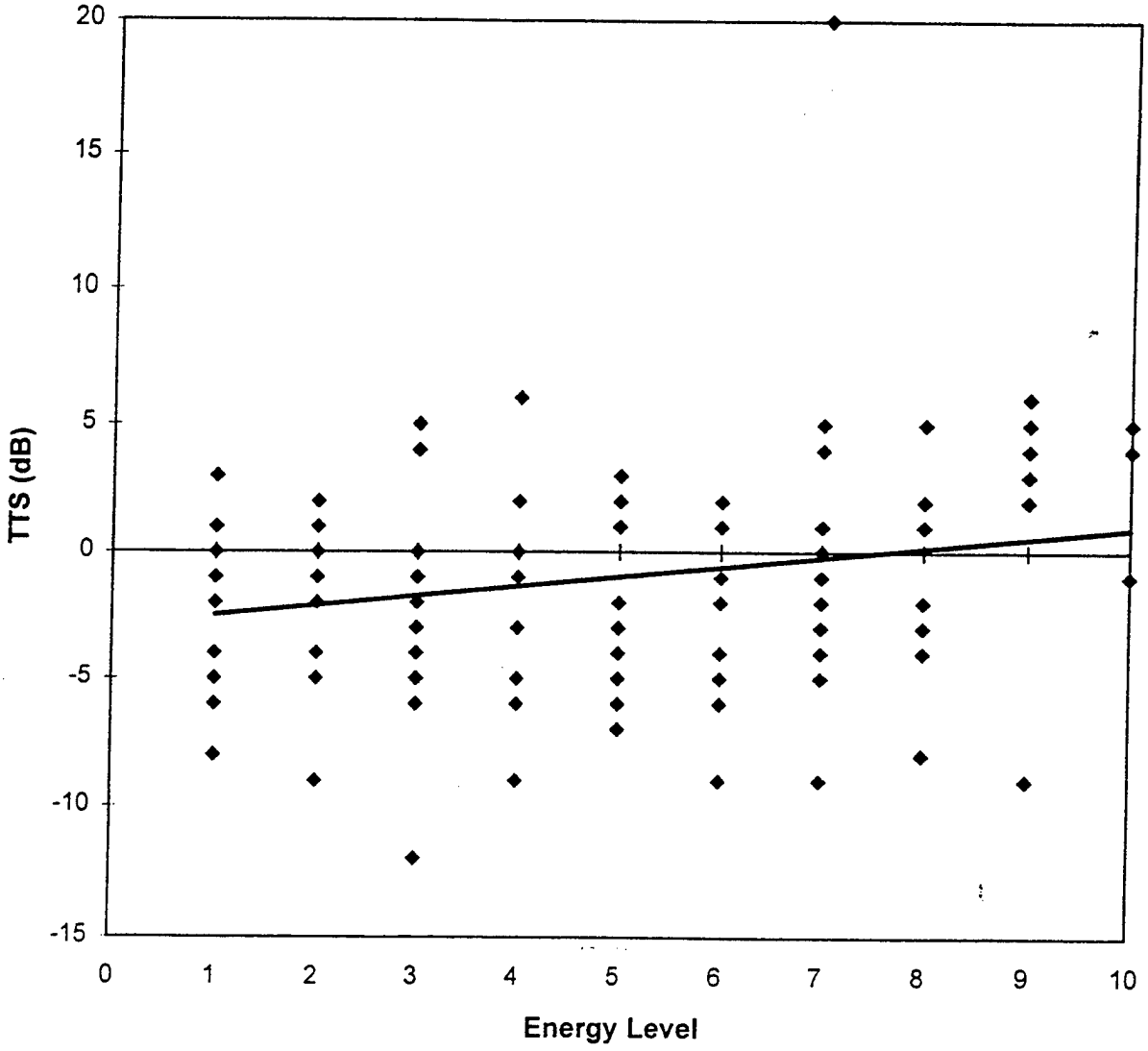


Figure III-24. Regression Analysis vs. Energy Level, 500 Hz, French No. 1 Plug.

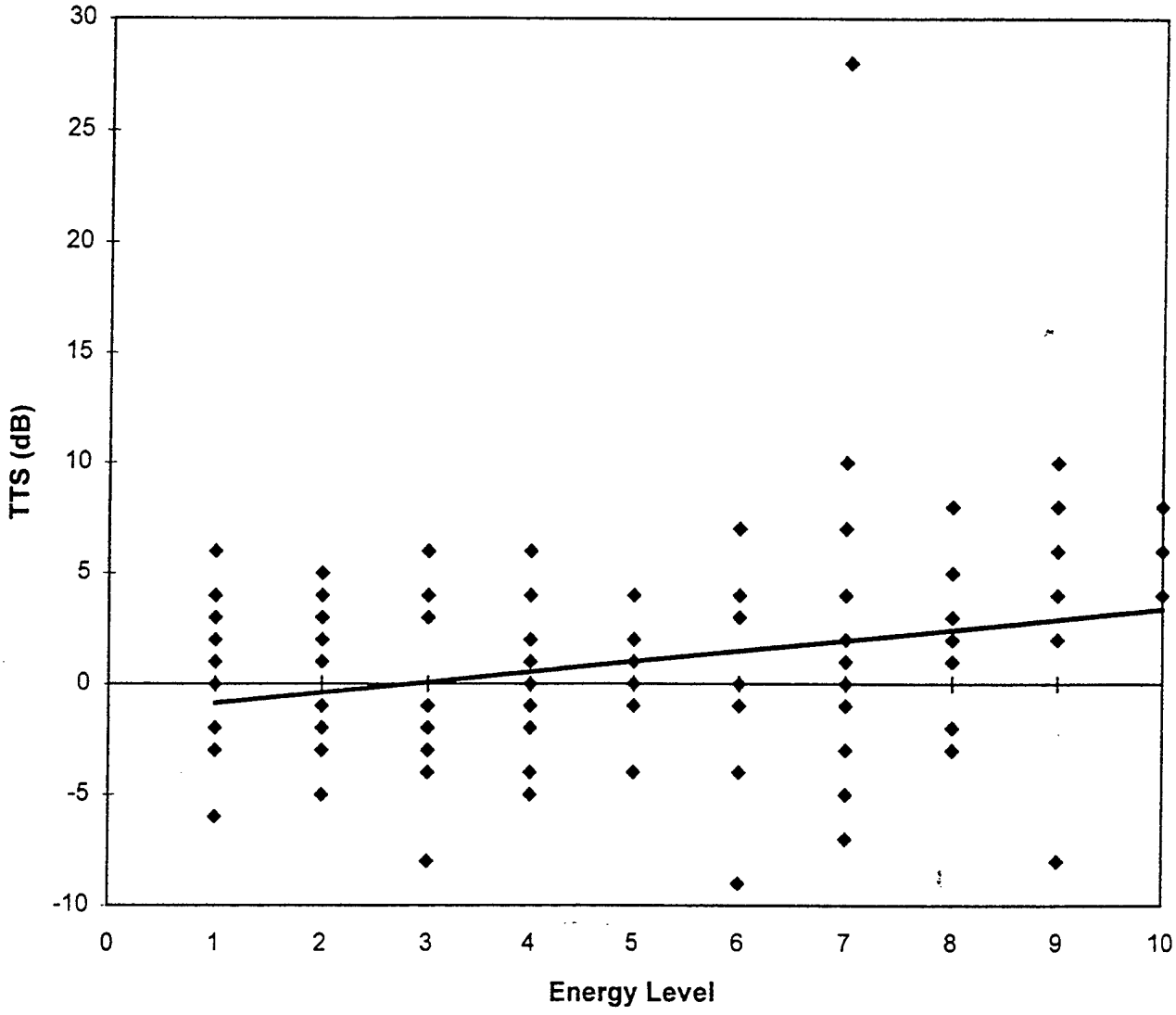


Figure III-25. Regression Analysis of TTS vs. Energy Level, 1000 Hz, French No. 1 Plug.

Table III-15

Results of Linear Regression of TTS vs. Energy Level, French No. 1 Plug

Frequency, Hz	Slope	Y-Intercept	R	t Stat	Significance F
125	-0.05	-0.57	0.03	-0.34	0.73
250	0.19	-0.18	0.14	1.46	0.15
500	0.38	-2.89	0.23	2.56	0.01
1000	0.47	-1.35	0.27	3.05	0.00
2000	0.10	0.20	0.05	0.54	0.59
3000	-0.14	-0.09	0.08	-0.82	0.42
4000	0.15	-1.38	0.07	0.78	0.44
6000	0.07	-0.28	0.04	0.44	0.66
8000	-0.28	1.43	0.18	-1.97	0.05

c. E.A.R.® Foam Plug, Right Ear

(1). Summary of Auditory Failures

When a subject had a failure with one of the nonlinear plugs such that it was not reasonable to continue further exposure, the subject was offered the option to continue exposures with the E.A.R.® foam plug. This was considered second-level hearing protection. Two subjects used second-level hearing protection during the French No. 1 Plug Study and one subject used second-level hearing protection during the Rucker Plug Study. Furthermore, during the Perforated Plug Study, completed in 1993, there were seven subjects who were started on second-level hearing protection. There were no audiometric failures against second-level hearing protection for any of these subjects. Thus, the TTS of these 10 subjects will be combined and analyzed further.

(2). Matrix Status

The number of subjects that can be considered to have been exposed to each matrix condition is shown in Figure III-26. Since there were no failures, the percent failures for each matrix condition was zero.

(3). TTS vs. Exposure Energy

As there were no failures due to excessive TTS, a regression of TTS vs. exposure energy should be fully valid. The summary of the regression analysis for each frequency is presented in Table III-16. Note that the 0.05 significance level was not reached for any frequency with a positive slope. There were two frequencies, 250 Hz and 6000 Hz, that were significant at the 0.05 significance level with negative slopes. A negative slope indicates an improvement in hearing as the energy increased. The frequency, 1000 Hz, with the greatest positive slope is shown in Figure III-27.

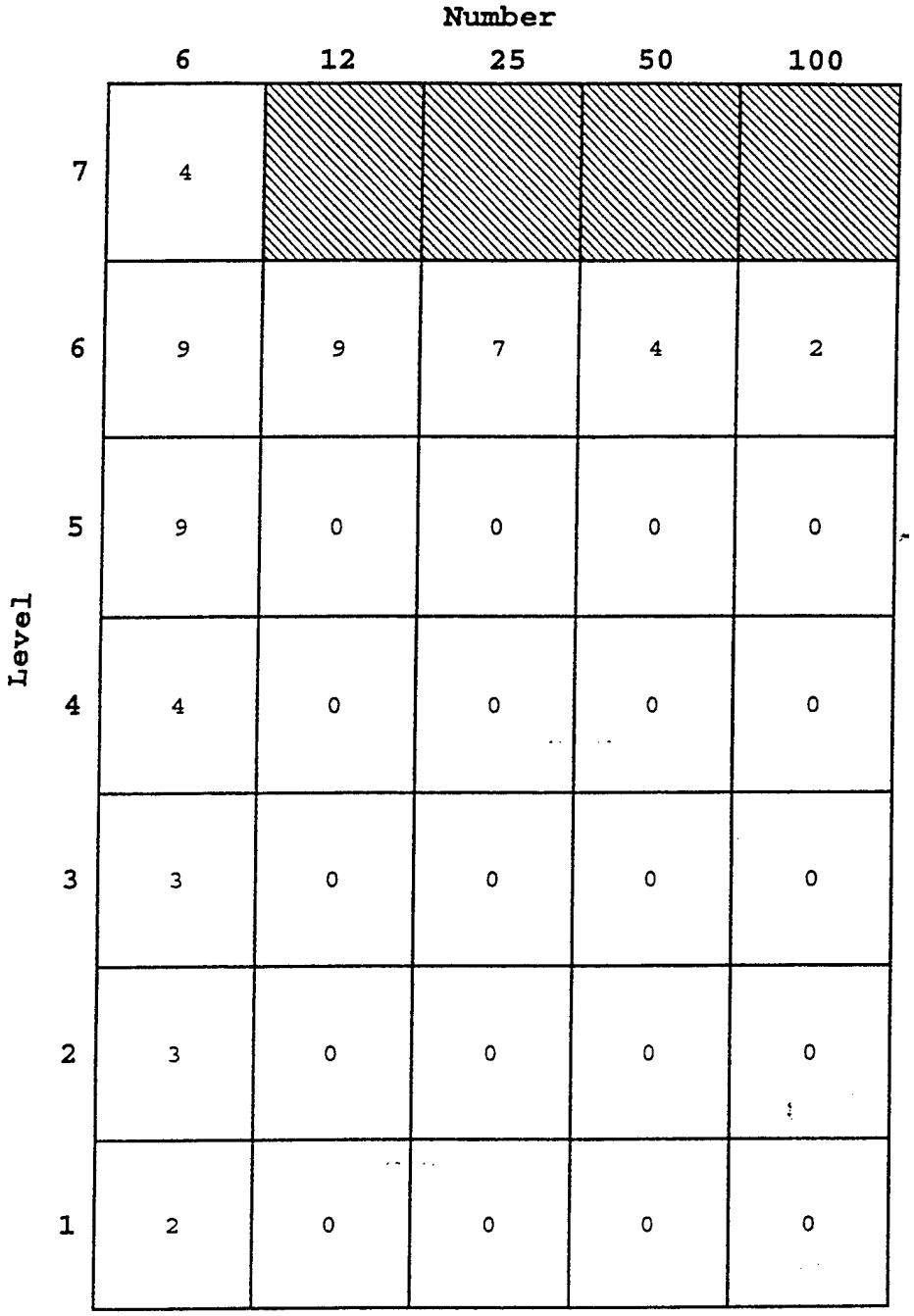


Figure III-26. Number of Subjects That Were Exposed to the Indicated Matrix Condition While Using Second-Level Hearing Protection (E.A.R.® Foam Plug) for the 3-M Distance.

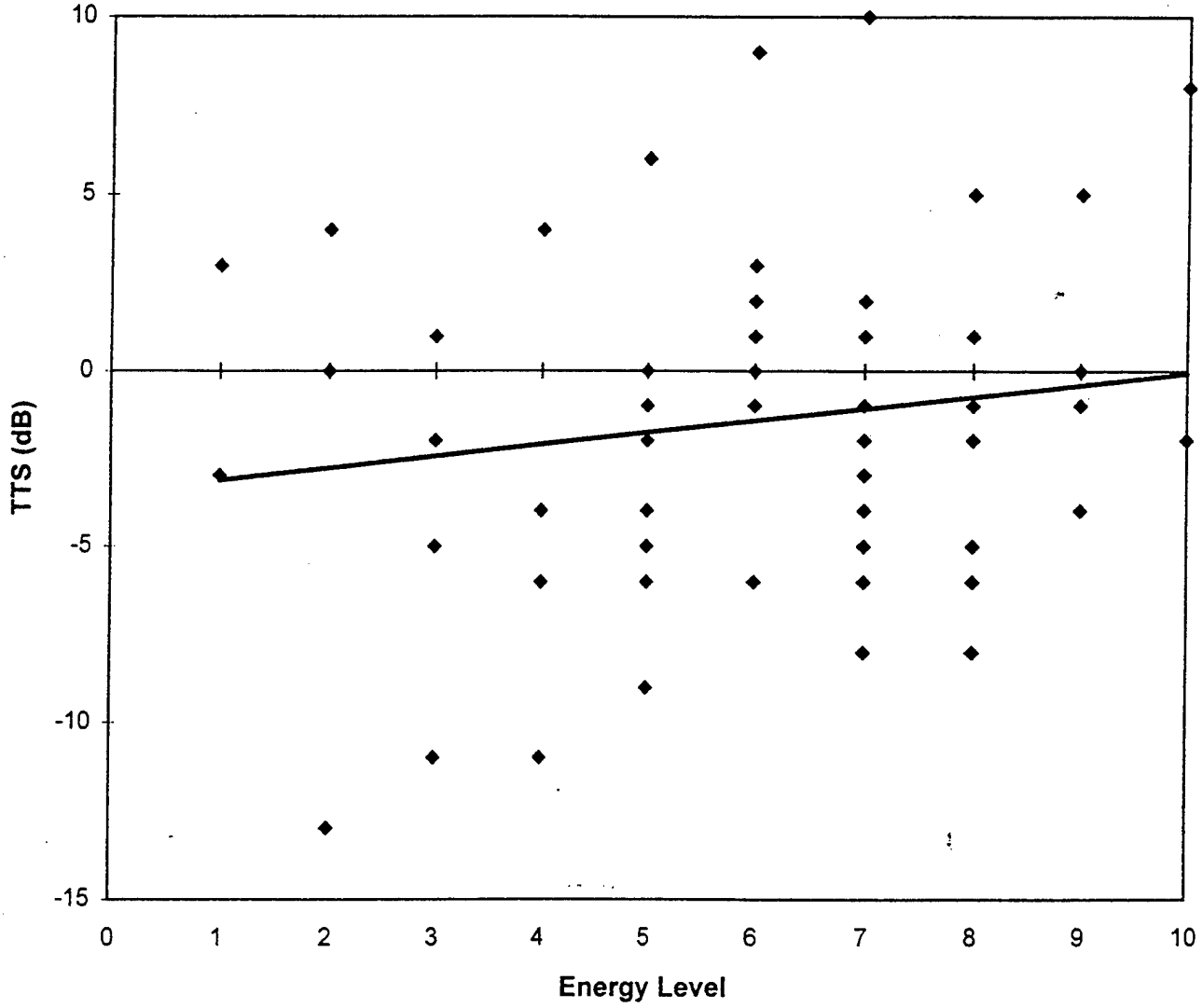


Figure III-27. Regression Analysis, TTS vs. Energy Level, Right Ear, E.A.R.® Foam Plug, 1000 Hz.

Table III-16

Results of Regression Analysis of TTS vs. Energy Level
E.A.R.® Foam Plug, Right Ear, 10 Subjects

Frequency, Hz	Slope	Y-Intercept	R	t Stat	Significance F
125	-0.10	-0.36	0.06	-0.50	0.62
250	-0.43	1.57	0.27	-2.27	0.03
500	-0.07	-1.70	0.04	-0.35	0.72
1000	0.34	-3.49	0.15	1.26	0.21
2000	0.18	-1.59	0.08	0.65	0.52
3000	-0.19	0.76	0.10	-0.80	0.42
4000	0.09	-2.57	0.04	0.33	0.74
6000	-0.61	2.22	0.25	-2.04	0.05
8000	-0.57	3.68	0.18	-1.47	0.15

d. E.A.R.® Foam Plug, Left Ear

(1). Summary of Audiometric Failures

Regardless of which plug was worn in the right ear, an E.A.R.® foam plug was worn in the left ear for all the nonlinear plug and perforated plug subjects. Thus, 27 subjects of the nonlinear plug as well as the 19 subjects of the perforated plug can be analyzed.

There were no audiometric failures for these 46 subjects. Because the left ear was shielded from the blast, the actual exposure to the left ear was slightly less.

(2). Matrix Status

The number of subjects that were exposed to each matrix condition is shown in Figure III-28. Since there were no failures, the percent failure was zero for all matrix conditions.

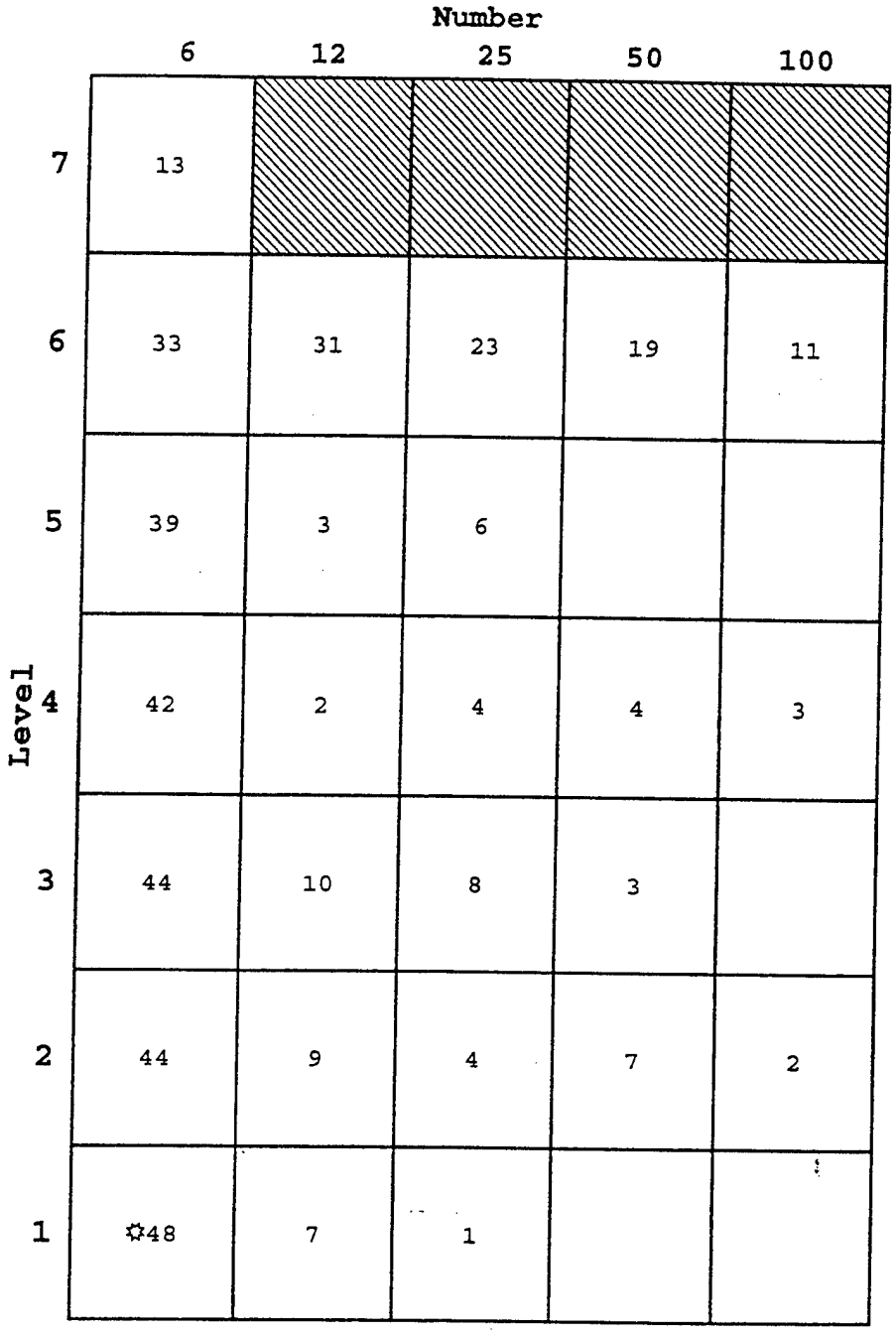


Figure III-28. Number of Subjects Exposed to the Stated Matrix Condition with the E.A.R.® Foam Plug, Left Ear. Number of subjects was 46 from both the perforated plug study and the nonlinear plug study. *In two cases (once with first-level hearing protection and once with second-level hearing protection), subjects passed the matrix condition twice.

(3). TTS vs. Exposure Energy

Because the left ear was tested after the right ear, the first test on the left ear was not started until 7.5 minutes after the exposure. This would mean that any TTS seen in the left ear would have had a slightly longer time to recover. However, a regression analysis should be reasonably valid. There is a problem that a more sensitive subject might have had a TTS in his right ear, thus, dropping him before he had time to develop a TTS in his left ear. This would reduce the chance of finding a significant effect. With this in mind, the regression analysis is presented in Table III-17. There was no significant effect noticed at any frequency. The frequency with the greatest positive slope was 125 Hz. The data for this frequency are plotted in Figure III-29.

Table III-17

Results of Regression Analysis of TTS vs. Energy Level, E.A.R.® Foam Plug, Left Ear, 46 Subjects

Frequency, Hz	Slope	Y-Intercept	R	t Stat	Significance F
125	0.15	-1.18	0.08	0.15	0.11
250	-0.03	-0.87	0.01	-0.30	0.77
500	-0.11	-1.47	0.04	-0.85	0.40
1000	-0.04	-1.02	0.02	-0.50	0.62
2000	0.08	-1.26	0.05	1.09	0.28
3000	-0.02	-1.56	0.02	-0.32	0.75
4000	-0.04	-1.64	0.02	-0.52	0.60
6000	-0.06	-0.60	0.02	-0.51	0.61
8000	0.05	0.55	0.02	0.43	0.67

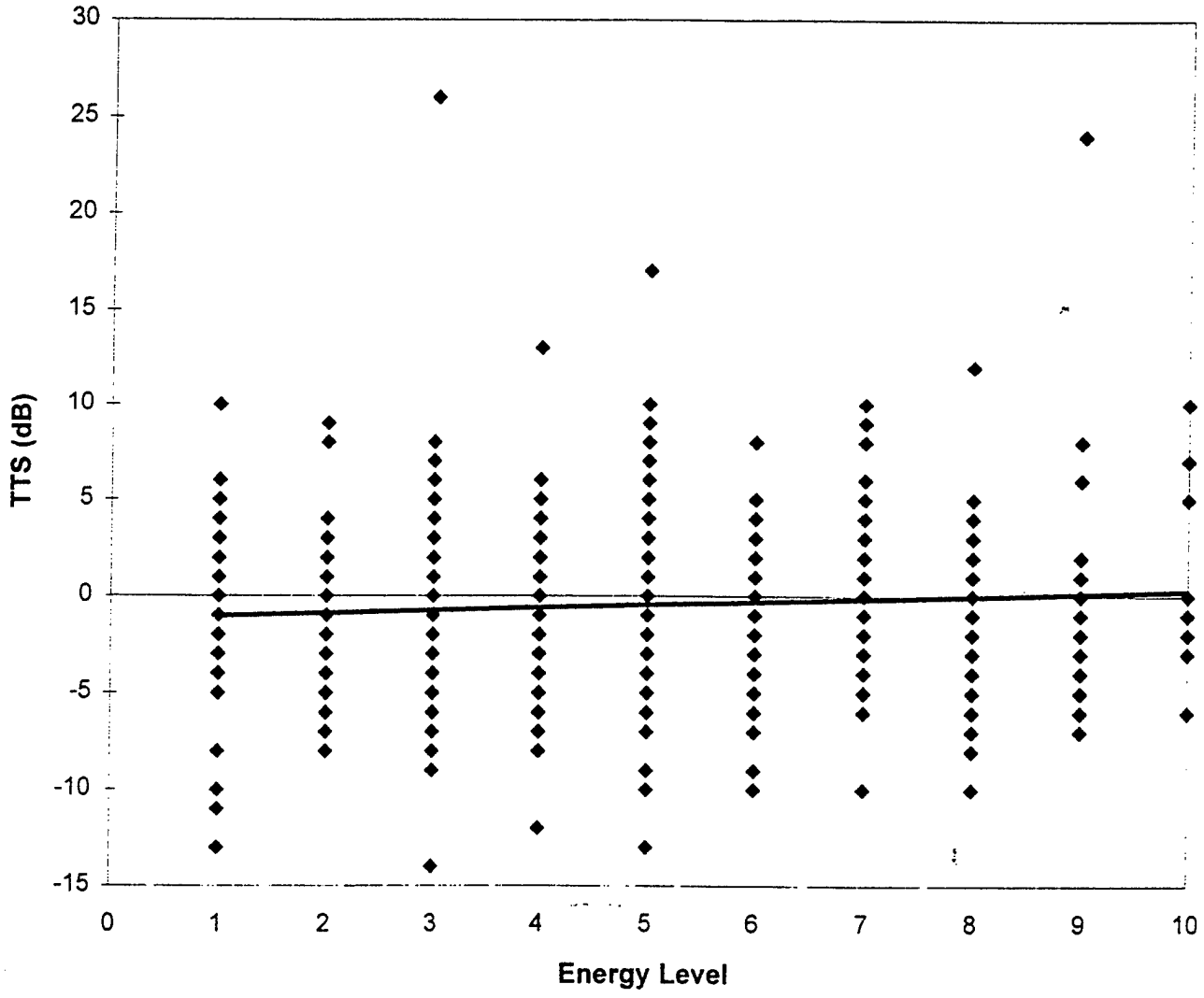


Figure III-29. Regression Analysis, TTS vs. Energy Level, E.A.R.® Foam Plug, Left Ear, 125 Hz.

e. Pre- and Post Audiograms

When the subjects first arrived in Albuquerque, they were given two audiograms by the Lovelace Audiology Department. As part of their exit physical, they were given two more audiograms by Lovelace. Historically, for the 273 subjects in the previous studies, the second or post audiograms have always been slightly better (improved hearing) than the preaudiograms. With the subjects in this nonlinear study, there seemed to be numerous subjects whose post audiograms were elevated by 10 dB in their left ear at the higher frequencies. Table III-18 summarizes the Lovelace preaudiogram minus post audiogram differences for the 27 subjects. Note that there are no significant differences in the right or test ear. In the left or nontest ear, there are differences at 4 kHz significant to the 0.05 confidence level. For the frequency of 6 kHz to 8 kHz, the differences are significant to the 0.01 confidence level.

It is not clear why these significant changes are present. The Lovelace audiometers were not calibrated during this period. If the audiometric data taken at the BOP site are used, a different result emerges. Table III-19 shows the mean difference of each subject's baseline minus their last audiogram taken during the study. This last audiogram may have been 1 hour after their last blast exposure, or some other event in case of an elective failure. Note that there is no significant difference between the baseline and the last audiogram except at 3 kHz in the right ear. But this difference is negative, indicating better hearing than the baseline. The left ear frequencies of 4 kHz and 6 kHz are also negative. So, these results are just counter to the Lovelace results.

A third set of data available is the data from the audioscan audiometer. Each subject's last test can then be compared to their baseline. Since this test takes measurements up to 16 kHz, the octave band from 8 kHz to 16 kHz may also be pertinent to the question. Since the audioscan takes 64 points per octave, the table breaks the data into octave bands from 125 Hz to 16 kHz. For this analysis, the 64 points of each band are averaged then compared to the baseline. The differences were analyzed for the seven subjects. Table III-21 summarizes the results. The mean differences are all negative for both ears for both frequencies, indicating an improvement in hearing for the last audiogram.

Table III-18

Summary of Pre- and Post Audiogram Differences
(Lovelace Data, 27 Subjects)

Right Ear	Frequency Range, Hz								
	125	250	500	1000	2000	3000	4000	6000	8000
Mean	-0.46	0.00	0.00	-0.93	-0.65	0.46	0.65	0.65	1.57
Standard Error	0.85	0.57	0.61	0.70	0.61	0.52	0.73	0.80	1.00
Median	0.00	0.00	0.00	-2.50	0.00	0.00	0.00	0.00	2.50
Mode	-5.00	2.50	-2.50	-2.50	0.00	2.50	0.00	0.00	-2.50
Standard Deviation	4.44	2.94	3.18	3.61	3.15	2.69	3.77	4.14	5.20
Sample Variance	19.73	8.65	10.10	13.05	9.90	7.23	14.23	17.11	26.99
Kurtosis	-1.07	0.26	-0.15	0.05	-0.06	-1.02	-0.42	1.35	-0.56
Skewness	0.48	-0.46	0.61	0.63	0.03	-0.20	0.10	-0.56	0.09
Range	12.50	12.50	12.50	15.00	12.50	10.00	15.00	20.00	20.00
Minimum	-5.00	-7.50	-5.00	-7.50	-7.50	-5.00	-7.50	-10.00	-7.50
Maximum	7.50	5.00	7.50	7.50	5.00	5.00	7.50	10.00	12.50
Sum	-12.50	0.00	0.00	-25.00	-17.50	12.50	17.50	17.50	42.50
Count	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Confidence Level(95.0%)	**1.76**	**1.16**	**1.26**	**1.43**	**1.24**	**1.06**	**1.49**	**1.64**	**2.06**

Left Ear	Frequency Range, Hz								
	125	250	500	1000	2000	3000	4000	6000	8000
Mean	0.74	0.93	0.74	0.00	0.37	1.20	2.41	3.89	2.59
Standard Error	0.83	0.77	0.69	0.82	0.69	0.67	1.14	0.93	0.86
Median	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.50	2.50
Mode	-2.50	0.00	0.00	-2.50	0.00	0.00	0.00	0.00	2.50
Standard Deviation	4.32	3.99	3.59	4.27	3.58	3.49	5.94	4.82	4.47
Sample Variance	18.66	15.94	12.89	18.27	12.84	12.20	35.33	23.24	19.94
Kurtosis	0.42	0.15	0.66	0.79	0.16	3.31	7.21	-0.73	0.46
Skewness	-0.16	0.32	0.53	0.35	0.06	1.32	2.22	0.55	0.33
Range	20.00	17.50	15.00	20.00	15.00	17.50	30.00	15.00	17.50
Minimum	-10.00	-7.50	-5.00	-10.00	-7.50	-5.00	-5.00	-2.50	-5.00
Maximum	10.00	10.00	10.00	10.00	7.50	12.50	25.00	12.50	12.50
Sum	20.00	25.00	20.00	0.00	10.00	32.50	65.00	105.00	70.00
Count	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Confidence Level(95.0%)	**1.71**	**1.58**	**1.42**	**1.69**	**1.42**	**1.38**	**2.35**	**1.91**	**1.77**

Table III-19

Summary of Differences Between Baseline and Last Audiograms Taken Using the BOP System

Right Ear	Frequency Range, Hz								
	125	250	500	1000	2000	3000	4000	6000	8000
Mean	0.19	0.07	-1.33	0.26	0.89	-1.74	-1.00	-0.93	-1.33
Standard Error	0.85	0.68	0.78	0.77	0.73	0.65	0.81	0.73	0.80
Median	0.00	1.00	-2.00	0.00	0.00	-2.00	0.00	-1.00	-1.00
Mode	-2.00	4.00	-2.00	-1.00	-2.00	-2.00	0.00	-4.00	-4.00
Standard Deviation	4.43	3.53	4.08	4.02	3.78	3.38	4.22	3.78	4.17
Sample Variance	19.62	12.46	16.62	16.12	14.26	11.43	17.85	14.30	17.38
Kurtosis	0.83	-1.15	1.84	3.00	-0.25	0.10	-0.01	0.12	-0.57
Skewness	0.56	-0.21	-0.87	-0.59	0.37	0.11	-0.63	-0.24	-0.09
Range	20.00	12.00	19.00	22.00	16.00	14.00	17.00	17.00	16.00
Minimum	-8.00	-6.00	-13.00	-12.00	-6.00	-8.00	-11.00	-10.00	-10.00
Maximum	12.00	6.00	6.00	10.00	10.00	6.00	6.00	7.00	6.00
Sum	5.00	2.00	-36.00	7.00	24.00	-47.00	-27.00	-25.00	-36.00
Count	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Confidence Level(95.0%)	**1.75**	**1.40**	**1.61**	**1.59**	**1.49**	**1.34**	**1.67**	**1.50**	**1.65**

Left Ear	Frequency Range, Hz								
	125	250	500	1000	2000	3000	4000	6000	8000
Mean	0.63	0.15	-1.19	-0.15	0.59	-1.22	-1.41	-1.22	1.33
Standard Error	0.98	1.04	0.99	0.87	0.90	0.64	0.71	1.01	1.02
Median	0.00	0.00	0.00	-1.00	0.00	-1.00	-1.00	0.00	2.00
Mode	2.00	-3.00	-2.00	-1.00	0.00	1.00	0.00	2.00	0.00
Standard Deviation	5.09	5.42	5.13	4.53	4.67	3.33	3.69	5.27	5.31
Sample Variance	25.93	29.36	26.31	20.52	21.79	11.10	13.64	27.79	28.23
Kurtosis	9.61	0.34	2.13	-0.39	-0.22	-1.18	2.29	2.54	1.56
Skewness	2.38	0.70	-1.11	0.42	0.56	-0.12	-1.13	-1.24	-0.44
Range	28.00	22.00	22.00	17.00	17.00	11.00	17.00	25.00	27.00
Minimum	-7.00	-8.00	-16.00	-7.00	-6.00	-7.00	-13.00	-18.00	-13.00
Maximum	21.00	14.00	6.00	10.00	11.00	4.00	4.00	7.00	14.00
Sum	17.00	4.00	-32.00	-4.00	16.00	-33.00	-38.00	-33.00	36.00
Count	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Confidence Level(95.0%)	**2.01**	**2.14**	**2.03**	**1.79**	**1.85**	**1.32**	**1.46**	**2.09**	**2.10**

Table III-20

Summary of Differences Between Baseline and Last Audiogram Taken Using the Audioscan Audiometer

Left Ear	Frequency Range, Hz						
	125-250	250-500	500-1000	1000-2000	2000-4000	4000-8000	8000-16000
Mean	-1.60	-2.28	-2.69	-1.15	-0.88	-0.38	-4.64
Standard Error	1.24	0.82	0.78	0.68	0.66	0.83	1.36
Median	-1.67	-1.83	-2.77	-0.82	-1.11	-0.25	-2.59
Mode	0.00	#N/A	#N/A	#N/A	#N/A	0.00	-1.67
Standard Deviation	6.44	4.25	4.08	3.51	3.44	4.30	7.07
Sample Variance	41.47	18.08	16.62	12.32	11.86	18.53	49.92
Kurtosis	6.65	1.54	1.76	4.74	5.80	3.51	0.12
Skewness	0.81	-0.39	-0.31	-0.15	0.20	0.47	-0.67
Range	38.17	21.06	20.51	20.85	21.34	23.42	28.84
Minimum	-17.28	-13.44	-14.00	-11.94	-11.34	-11.76	-20.69
Maximum	20.89	7.63	6.52	8.91	10.00	11.67	8.15
Sum	-43.32	-61.46	-72.64	-31.16	-23.86	-10.22	-125.33
Count	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Confidence Level(95.0%	**2.55**	**1.68**	**1.61**	**1.39**	**1.36**	**1.70**	**2.79**

Right Ear	Frequency Range, Hz						
	125-250	250-500	500-1000	1000-2000	2000-4000	4000-8000	8000-16000
Mean	-1.66	-2.16	-1.59	-1.63	-1.70	-1.46	-2.48
Standard Error	0.72	0.60	0.58	0.35	0.38	0.33	1.14
Median	-1.25	-2.83	-2.22	-1.91	-1.63	-1.44	-2.52
Mode	#N/A	-4.66	#N/A	#N/A	-1.00	0.00	#N/A
Standard Deviation	3.76	3.13	3.01	1.84	2.00	1.71	5.93
Sample Variance	14.11	9.82	9.08	3.40	3.99	2.93	35.17
Kurtosis	0.23	0.38	1.02	0.45	-0.04	0.15	0.73
Skewness	-0.42	0.34	0.92	0.45	0.23	-0.15	-0.74
Range	15.64	14.33	12.00	8.32	7.89	7.40	24.45
Minimum	-11.23	-9.02	-6.13	-5.31	-5.31	-4.98	-18.31
Maximum	4.41	5.31	5.87	3.01	2.58	2.42	6.14
Sum	-44.90	-58.31	-43.02	-44.08	-45.78	-39.52	-67.08
Count	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Confidence Level(95.0%	**1.49**	**1.24**	**1.19**	**0.73**	**0.79**	**0.68**	**2.35**

#N/A = not analyzed

These differences were significant for almost all frequencies. These results are also just the opposite from the Lovelace exit audiograms.

There is no clear explanation for the discrepancy. Two audiograms approximately 1 hour apart were given at Lovelace, so it does not seem likely that the elevation at 4, 6, and 8 kHz was entirely due to lack of attention or fatigue even though these frequencies were the last tested. Nevertheless, the results of the audiometry accomplished during the actual exposures are considered more pertinent and should be given more weight. For this reason, we concluded that the E.A.R.® foam plug did protect the left or shielded ear adequately during all exposure frequencies.

4. Nonauditory and Other

a. Rucker Plug

(1). Nonauditory Injury

Of the 13 subjects that started the study, there were no nonauditory injuries. The stool guaiacs given after Level 7 were all negative.

(2). Acceptability Charts/Elective Failures

The acceptability of the 3-m distance with the Rucker Plug is shown in Figure III-30. The subjects were not exposed to all conditions, of course, but were asked to provide the best judgment as to the acceptability of the conditions that they did not receive. There was a distinct break between condition 7/6 and 6/6.

Figure III-31 illustrates the data from asking the subjects to grade acceptability on a scale of 1 to 4.

The summary of elective failures is shown in Table III-21.

Table III-21

Summary of Elective Failures
Rucker Plug, 3-m Distance

Subject	Level 7 Elective Failure	Condition Elected Not to Go	Election Stopped Exposure
2012		6/12	Yes
2013	Yes		No
2015		6/25	Yes
2016		2/100	Yes
2023		3/50	Yes
2025		2/100	Yes
2033	Yes		No
2035	Yes	6/100	Yes
2042	Yes	6/12	Yes*

* Second-level hearing protection.

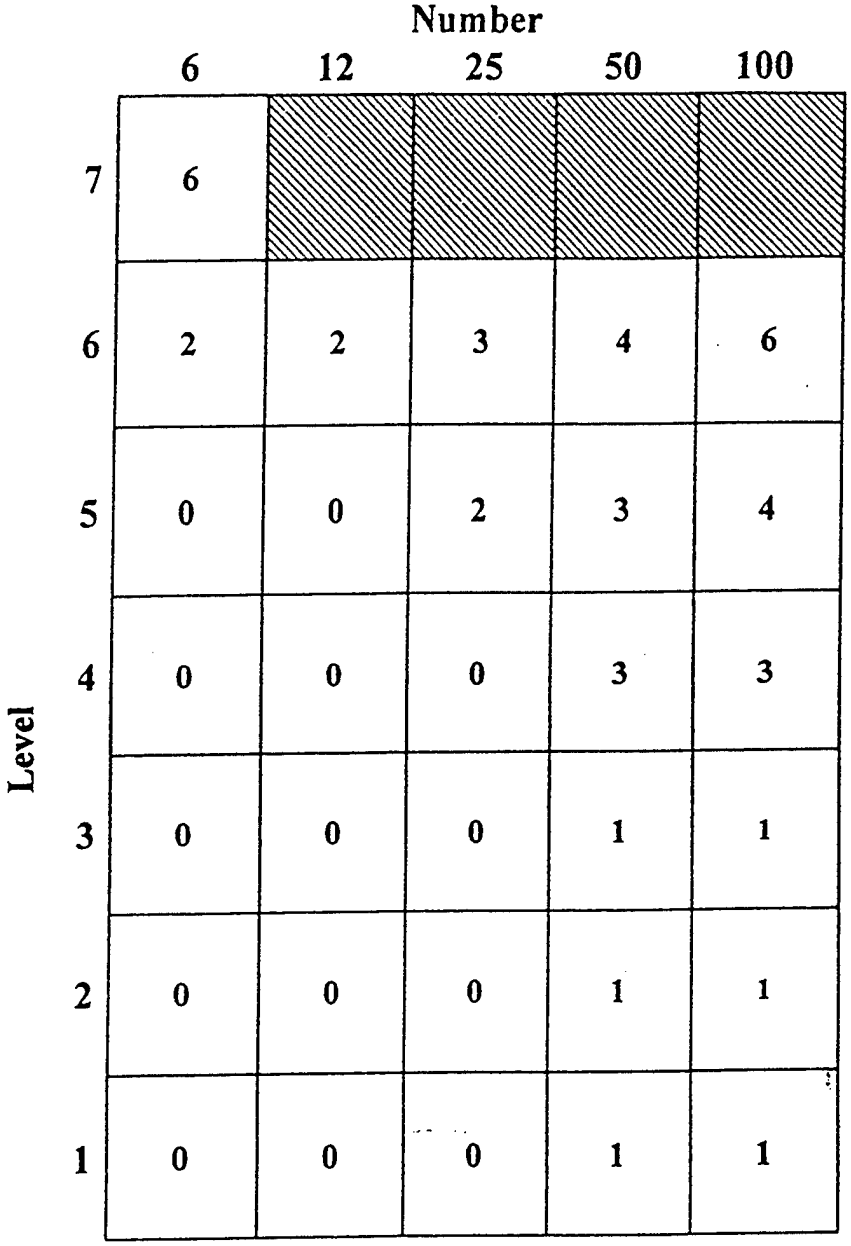


Figure III-30. The Total Number Out of Seven Subjects Who Marked the Above Conditions as Unacceptable, Rucker Plug.

Level	Number: 6	12	25	50	100
7	4 7 3 0 2 0 1 0				
6	4 2 3 0 2 2 1 3	4 1 3 1 2 2 1 3	4 1 3 1 2 4 1 1	4 2 3 4 2 0 1 1	4 5 3 1 2 1 1 0
5	4 0 3 1 2 2 1 4	4 0 3 2 2 1 1 4	4 0 3 2 2 2 1 3	4 2 3 1 2 2 1 2	4 3 3 1 2 2 1 1
4	4 0 3 1 2 1 1 5	4 0 3 1 2 1 1 5	4 0 3 1 2 1 1 5	4 0 3 3 2 0 1 4	4 1 3 2 2 1 1 3
3	4 0 3 0 2 1 1 6	4 0 3 0 2 2 1 5	4 0 3 0 2 2 1 5	4 0 3 1 2 2 1 4	4 0 3 2 2 1 1 4
2	4 0 3 0 2 0 1 7	4 0 3 0 2 0 1 7	4 0 3 0 2 0 1 7	4 0 3 1 2 0 1 6	4 0 3 1 2 0 1 6
1	4 0 3 0 2 0 1 7	4 0 3 0 2 0 1 7	4 0 3 0 2 0 1 7	4 0 3 1 2 0 1 6	4 0 3 1 2 0 1 6

Please rank each block for acceptability to train using numbers 1-4 as follows:

1. Acceptable.
2. Acceptable but would not look forward to day in which exposure occurred.
3. Marginally acceptable but would be concerned each time I was exposed.
4. Unacceptable.

Figure III-31. Acceptability Rating of the 3-M Distance, Rucker Plug, Seven Subjects Responded.

(3). Exit Questionnaires

The results of the exit questionnaires are shown in Table III-22. The summary of all the subjects that used muffs or the perforated plug of the previous studies is included for comparison purposes. The results are quite consistent except for the Rucker Plug. Questions 1, 3, and 4 of the first set of questions indicated a problem with the recruitment briefing. Therefore, there were more fair and poor responses than normal. Questions 4 and 5 of the second set of questions (the intensity of the blast and the physical discomfort questions) are worth studying. A greater percentage of the subjects using the nonlinear plugs (85%) thought the blasts were more intense (56%) than those wearing muffs. Likewise, a somewhat greater percentage of the subjects wearing the nonlinear plugs (48%) than those wearing muffs (38%) thought the physical discomfort from the blasts was worse than they expected.

The increase in the percentage that believed the blasts were more intense was supported by many subjects mentioning to the P.I. that the sounds seemed to go right through the nonlinear plug. With an orifice in the plug, it is not unexpected for the blasts to sound louder. This sensation of loudness, however, may cause the blasts to be less acceptable.

TABLE III-22

Exit Questionnaire Results

A. INTRODUCTION

The purpose of this questionnaire is to find out what you thought about the study and your part in it. The information you and others give concerning various aspects of the study will be used to (1) identify any problem areas which are in need of improvement, and (2) help monitor performance over the course of the study. Since there are some good and some bad aspects about being a part of this study, it is the only way we can accomplish this task.

Question	Group	Excellent	Good	Fair	Poor
1. Information you received before you agreed to participation in this study	Muff	104	81	20	7
	Perforated Plug	6	1	0	0
	Rucker Plug	0	0	1	12
	French Plug	3	4	5	1
2. How easy was it to get questions answered that you might have had about being part of the study?	Muff	135	68	8	1
	Perforated Plug	7	0	0	0
	Rucker Plug	2	9	2	0
	French Plug	6	6	1	0
3. Accuracy of information provided to you when you were recruited concerning medical tests you would be subjected to.	Muff	120	74	12	1
	Perforated Plug	7	0	0	0
	Rucker Plug	3	4	3	3
	French Plug	6	4	3	0

Table III-22 (Continued)

Question	Group	Excellent	Good	Fair	Poor
4. Accuracy of the information provided when you were recruited regarding the effects on you of actual blasts.	Muff	102	90	15	0
	Perforated Plug	6	1	0	0
	Rucker Plug	0	8	1	4
	French Plug	5	6	1	1

Please read the following statements and state whether you agree or disagree with each statement. Think about the experiences you had while being a part of the study. When you cannot respond to a statement from your own experience, you can respond according to the experiences of other volunteers you know who were participants or you can write "uncertain." There are no right or wrong answers. We just want your opinions.

Question	Group	Strongly Agree	Agree	Disagree	Strongly Disagree
1. All questions were answered before I agreed to come to Albuquerque and be a part of this study.	Muff	72	115	22	1
	Perforated Plug	3	4	0	0
	Rucker Plug	0	10	3	0
	French Plug	2	10	1	0
2. I felt pressured into agreeing to participate in this study.	Muff	1	4	47	157
	Perforated Plug	0	0	4	2
	Rucker Plug	0	0	9	4
	French Plug	2	2	6	3

Table III-22 (Continued)

Question	Group	Strongly Agree	Agree	Disagree	Strongly Disagree
3. The laryngoscopic exams were uncomfortable and I would have preferred they had not been done.	Muff	37	73	81	19
	Perforated Plug	1	4	1	1
	Rucker Plug	5	3	5	0
	French Plug	4	4	3	2
4. The actual blast tests were more intense than I expected.	Muff	16	94	78	20
	Perforated Plug	0	3	2	2
	Rucker Plug	3	7	3	0
	French Plug	4	8	1	0
5. The physical discomfort I felt from the blasts was worse than I anticipated.	Muff	7	42	121	33
	Perforated Plug	0	0	5	2
	Rucker Plug	1	7	4	1
	French Plug	1	4	7	2
6. Medical personnel always told me what to expect during examinations	Muff	0	17	75	117
	Perforated Plug	0	0	4	3
	Rucker Plug	1	1	9	2
	French Plug	1	1	5	6

Table III-22 (Continued)

Question	Group	Strongly Agree	Agree	Disagree	Strongly Disagree
7. Medical personnel always told me what to expect during examinations.	Muff	90	109	8	4
	Perforated Plug	2	5	0	0
	Rucker Plug	2	11	0	0
	French Plug	4	9	0	0
8. I need more break time between medical exams and tests.	Muff	3	21	138	48
	Perforated Plug	0	0	4	3
	Rucker Plug	0	6	6	1
	French Plug	0	2	6	5
9. My mental attitude was improved by participating in this study.	Muff	25	88	55	4
	Perforated Plug	1	6	0	0
	Rucker Plug	1	7	4	0
	French Plug	1	9	2	1
10. The medical personnel had plenty of time to do a good job.	Muff	66	141	5	0
	Perforated Plug	1	6	0	0
	Rucker Plug	0	13	0	0
	French Plug	6	6	1	0

Table III-22 (Continued)

Question	Group	Strongly Agree	Agree	Disagree	Strongly Disagree
11. I felt the military staff involved in the study were concerned about me personally.	Muff	121	85	12	
	Perforated Plug	3	4	0	
	Rucker Plug	5	6	0	
	French Plug	7	5	1	0
12. My sleep pattern was disturbed during my participation in this study.	Muff	8	19	135	70
	Perforated Plug	0	1	3	3
	Rucker Plug	0	4	7	2
	French Plug	0	1	7	5
13. I'm glad I agreed to participate in this study.	Muff	140	50	1	0
	Perforated Plug	3	3	1	0
	Rucker Plug	2	11	0	0
	French Plug	8	5	0	0
14. I think my being a part of this study will benefit military personnel	Muff	103	99	4	0
	Perforated Plug	3	4	0	0
	Rucker Plug	6	7	0	0
	French Plug	7	5	1	0

Table III-22 (Continued)

Question	Group	Strongly Agree	Agree	Disagree	Strongly Disagree
15. I would recommend to others that they agree to be a participant in this study.	Muff	103	96	7	1
	Perforated Plug	3	4	0	0
	Rucker Plug	2	8	2	1
	French Plug	3	9	1	0
16. The medical personnel treated me with care and concern.	Muff	105	114	1	0
	Perforated Plug	3	4	0	0
	Rucker Plug	3	9	1	0
	French Plug	6	6	1	0
17. Being a part of this study will benefit me later in life.	Muff	42	111	41	4
	Perforated Plug	2	5	0	0
	Rucker Plug	1	6	5	1
	French Plug	3	7	1	1

(4). Rank Order Charts

After a subject had been exposed to Level 7, he was asked to compare the levels by placing the Levels 2-6 between Levels 1 and 7. The results of five subjects responses are shown in Figure III-32. These results are typical when compared with those of the RACAL® muffs.

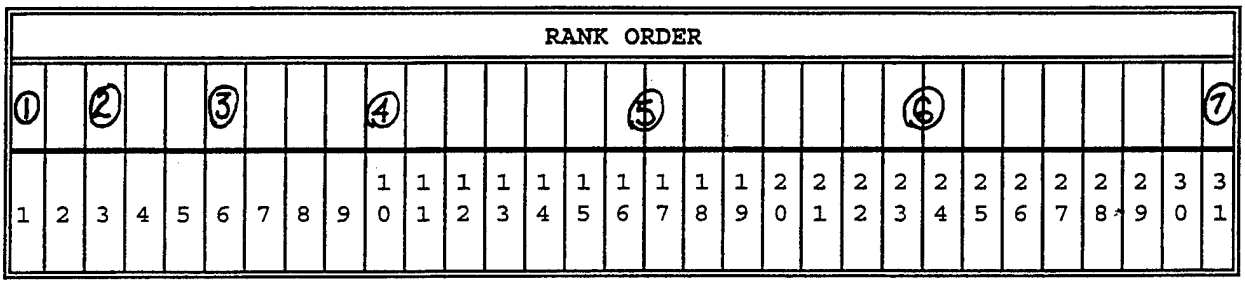


Figure III-32. Average Ranking of Five Subjects with Respect to the Difference Between Exposure Levels.

b. French No. 1 Plug

(1). Nonauditory Injury

Of the 14 subjects that participated in the study, the only nonauditory injuries were experienced by subject nos. 2056 and 2076. Subject 2056 had bruising on his arm due to the slapping effect of his BDU. This was the first time such bruising had been clearly observed since the 5-m exposures in 1990; although, subject 2013 had a trace of such bruising. This does not normally happen unless the BDU cloth is slightly damp. Subject 2056 caused his BDU to become damp by doing pushups between blasts.

Subject 2076 began to encounter sinus headaches after approximately shot no. 10 at Level 6. During condition 6/25, once he understood that this would be sufficient to go to condition 6/50, he came off the pad after shot 20 After shot 10, he stated that the blast seemed to go up through his nasal passage into his sinuses that caused a headache. His headache went away during the evening. He then was exposed to condition 6/50. Again, his headache started at shot 10 and became more severe until shot 20

and stayed constant until shot 40. After shot 40, the subject and the PI agreed that he should come off the pad. The subject stated that the headache of the 40-shot sequence was not as severe as the one of the 20-shot sequence. He did elect not be exposed to condition 6/100. The PI intends to count this as a nonauditory failure to Level 6 for the 3-m distance. This would be the first nonauditory failure for the 3-m distance of 70 subjects who have been exposed to condition 6/25 or greater.

(2). Acceptability Charts/Elective Failures

The acceptability of the 3-m distance is shown in Figures III-33 and III-34. There was a distinct break between Levels 6 and 7. In addition, it appears that the exposures were somewhat more acceptable with the French No. 1 Plug than the Rucker Plug.

Table III-23 summarizes the elective failures that occurred.

Table III-23

Summary of Elective Failures
French No. 1 Plug

Subject	Level 7 Elective Failure	Condition Elected Not to Go On	Election Stopped Exposure
2053	Yes	6/100	Yes
2056	Yes		No
2062	Yes	6/100	Yes
2063	Yes	5/50*	Yes*
2065	Yes	5/100	Yes
2072	Yes	6/100	Yes
2075	Yes	6/24* 5/25	Yes
2055	Yes	6/100**	Yes

* Second-level hearing protection.
** Stopped after 44 shots.

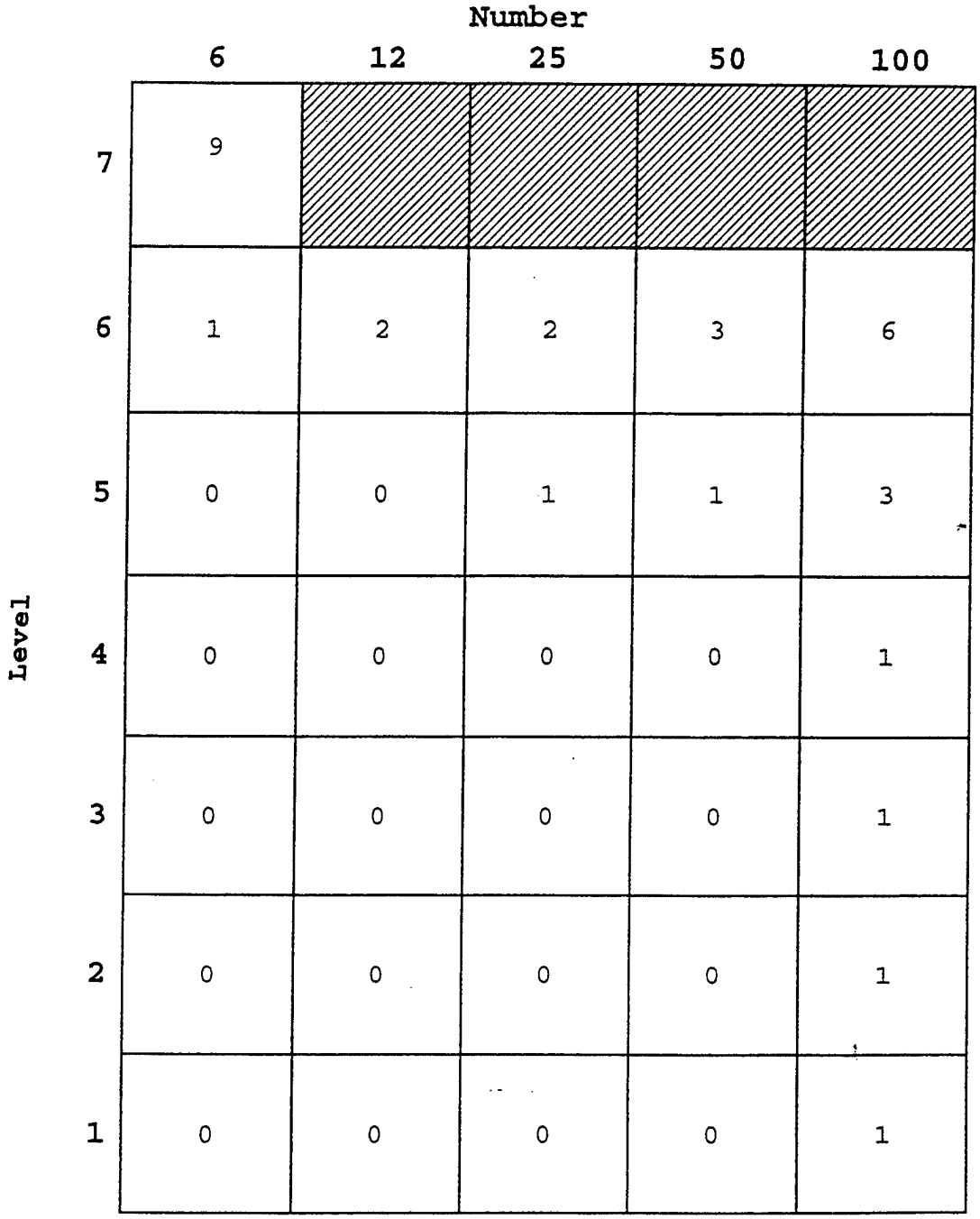
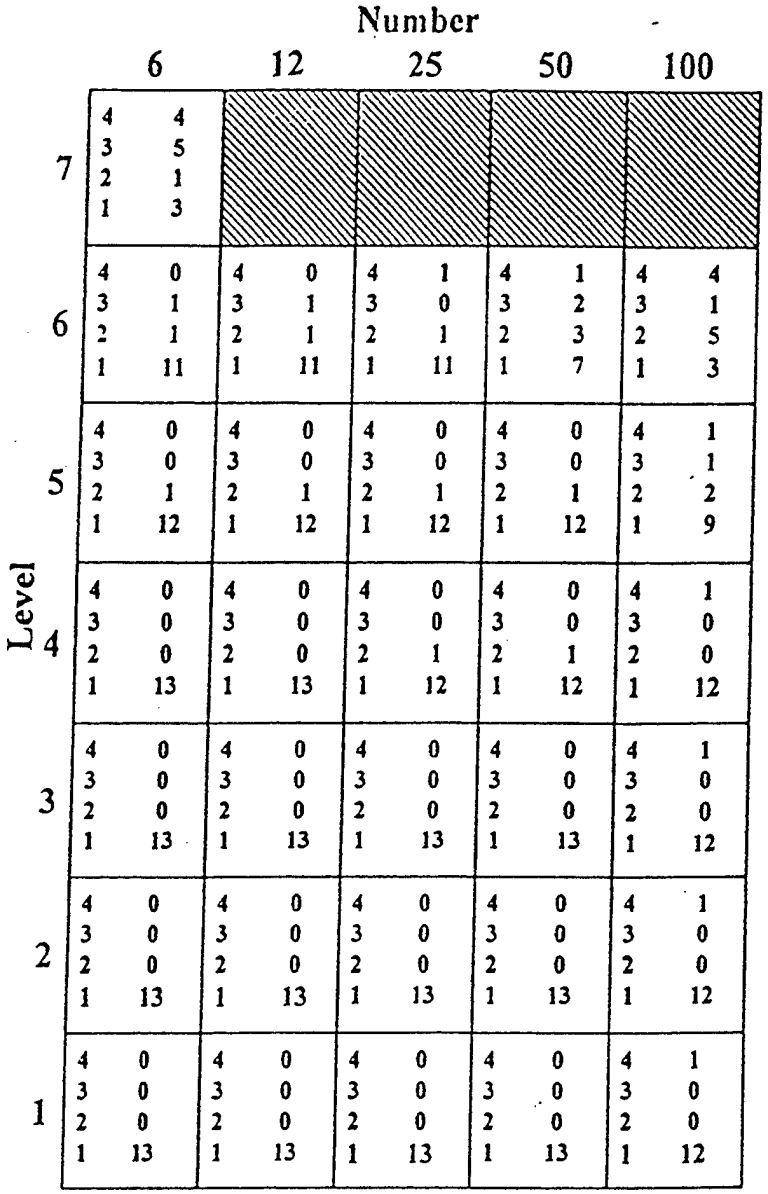


Figure III-33. The Total Number Out of 13 Subjects Who Marked the Above Conditions as Unacceptable, French No. 1 Plug.



Level	6	12	25	50	100
7	4 4 3 5 2 1 1 3				
6	4 0 3 1 2 1 1 11	4 0 3 1 2 1 1 11	4 1 3 0 2 1 1 11	4 1 3 2 2 3 1 7	4 4 3 1 2 5 1 3
5	4 0 3 0 2 1 1 12	4 0 3 0 2 1 1 12	4 0 3 0 2 1 1 12	4 0 3 0 2 1 1 12	4 1 3 1 2 2 1 9
4	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 0 3 0 2 1 1 12	4 0 3 0 2 1 1 12	4 1 3 0 2 0 1 12
3	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 1 3 0 2 0 1 12
2	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 1 3 0 2 0 1 12
1	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 0 3 0 2 0 1 13	4 1 3 0 2 0 1 12

Please rank each block for acceptability to train using numbers 1-4 as follows:

1. Acceptable.
2. Acceptable but would not look forward to day in which exposure occurred.
3. Marginally acceptable but would be concerned each time I was exposed.
4. Unacceptable.

Figure III-34. Acceptability Rating of the 3-M Distance, French No. 1 Plug, 13 Subjects Responded.

(3). Exit Questionnaire

The answers given by the subjects using the French No. 1 Plug were typical of the subjects using the muffs except questions 4 and 5 (see Table III-22). See discussion under Rucker Plug.

(4). Rank Order Charts

The comparison of the different levels was done by the four subjects that were exposed to Level 7. Although the greatest step was between Levels 4 and 5, the pattern is consistent with the results from the muff exposures (Figure III-35).

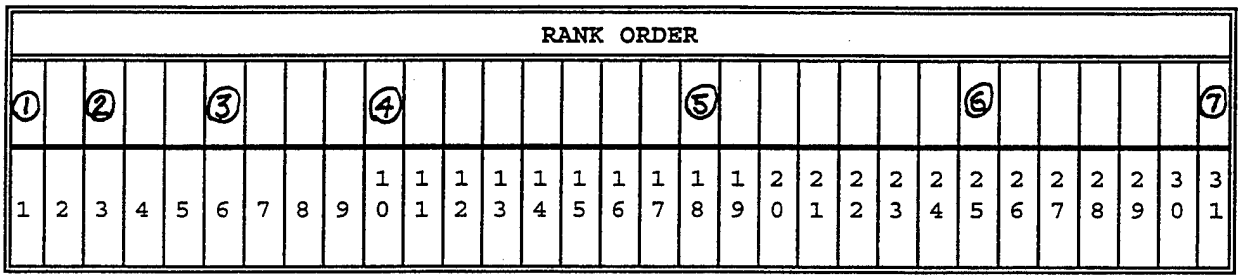


Figure III-35. Average Ranking of Four Subjects with Respect to the Difference Between Exposure Levels.

c. Performance Assessment Battery (PAB) Test Results (Both Plugs)

The results of the PAB testing was reviewed in two ways. A regression of pre- and post exposure differences is summarized in Table III-24. The data for each subject is provided in Appendix J. As with the Firing from an Enclosure Study, none of the regressions are significant. Basically, there is no correlation between pre- and post differences in PAB scores and the energy in the exposure condition for either the overall scores or the scores of the individual tasks.

The correlation of the overall post test scores vs. energy level shows a strong positive correlation of increasing score with energy level, Table III-25. Similar to the Firing from

an Enclosure Study, we believe that the subjects kept learning how to improve their score as the study progressed. Most of the subjects were proud of their scores and tried to do the best they could. The best place to make any drastic improvement was in the math task. This showed up in the very significant improvement in the math task vs. energy level, Table III-25. The other three tasks showed no significant correlation with energy level. Thus, the improvement in the overall PAB scores was almost entirely due to the improvement in the math scores.

Table III-24

Pre- and Post-Exposure Differences in Total PAB Score vs. Energy Step Level

Score	Slope	Y-Intercept	R	t Stat	Significance F
Total	0.18	11.46	0.01	0.10	0.92
Memory	0.31	0.55	0.04	0.53	0.59
Math	-0.04	10.98	0.00	-0.03	0.97
Visual	0.18	-2.11	0.02	0.28	0.78
Audio	-0.27	2.04	0.04	-0.65	0.52

Table III-25

The Post-Exposure Total PAB Score vs. Energy Step Level

Score	Slope	Y-Intercept	R	t Stat	Significance F
Total	7.05	312.8	0.22	3.42	0.00073
Memory	-0.03	79.3	0.0047	-0.072	0.9425
Math	6.059	122.9	0.283	4.47	0.0000118
Visual	-0.05	69.99	0.0059	-0.09	0.928
Audio	1.08	40.6	0.101	1.54	0.125

d. Medical Data (Rucker and French No. 1 Plugs)

The only clear effect that the level of the blast had on any of the subjects was the sinus headache of subject 2076. There were several incidents of minor headaches that were attributed to wearing the helmet. At the higher levels, the helmet would push against the head after each shot and some subjects had to readjust the fit in order to reduce the problem. The stool guaiacs of all the subjects exposed to Level 7 were negative. All laryngoscopic examinations were negative. The pre/post spirometry difference showed no significant correlation between energy pre/post differences (Table III-26). A positive value indicates that there is an improvement in the post-exposure value over the preexposure value.

A daily questionnaire (Figure III-36) was completed by the physician assistant/nurse practitioner for each subject prior to his exposure. Table III-27 is a summary of the preexposure complaints prior to the energy level. Thus, on the day prior to Energy Level 10 (condition 6/100), there were no medical complaints at all for the nine subjects exposed. As stated earlier, there were no new post-exposure complaints except for the one subject's headache. The pattern of the data of Table III-27 shows more response early in the study. By the end of the exposure sequences, the sore throats, upset stomachs, etc., had disappeared. This argues against the blasts causing any underlying problems. The last incident reported was for Energy Level 9 (abdomen, subject 2066). He reported with a case of diarrhea. His exposure was delayed a day because of this.

Table III-26

Pre-Post Exposure Spirometry Percent Change vs. Energy Level

Test Type	n	Slope	Intercept	R	Significance F	t Stat
FVC	76	0.47	-0.99	0.20	0.09	1.72
FEV 0.5	76	0.37	0.44	0.21	0.07	1.85
FEV 1	76	0.35	-0.39	0.20	0.09	1.74
FEF 25-75%	76	0.31	3.02	0.09	0.43	0.8
FEF M	76	-0.01	1.52	0.01	0.96	-0.06
FEF	76	-0.15	0.97	0.12	0.29	-1.07

FVC — Forced Vital Capacity. A vital capacity performed with a maximally forced expiratory effort; i.e., as hard and fast as possible. From this tracing, all flow rates may be analyzed.

FEV_T — Forced Expired Volume, timed. The volume of air expired at a specified time during the forced vital capacity. Generally, $FEV_{0.5}$ and FEV_1 are the most commonly measured values.

$FEF_{25-75\%}$ — Mean Forced Expiratory Flow during the middle half of the FVC.

FEF M — The maximum expiratory flow rate (MEFR).

FEF — Forced expiratory volume to forced vital capacity ratio, expressed as a percentage.

BLAST OVERPRESSURE STUDY

DAILY MEDICAL EVALUATION

PHYSICAL EXAMINATION

Date:_____

Name:_____

Social Security Number:_____

VITAL SIGNS:

TEMPERATURE [ ]°C. WEIGHT: [ ]KG

PULSE RATE [ ]/MIN PULSE REGULAR [ ]
(1-Yes; 2-No)

BP SITTING - RT [ ]MMHG
BP SITTING - LT [ ]MMHG
RESPIRATION [ ]/MIN

SUMMARY OF PHYSICAL EXAMINATION:

EYES:	[ ]	(1-Normal; 2-Abnormal)	P. 3
NOSE:	[ ]	(1-Normal; 2-Abnormal)	P. 3
SINUSES:	[ ]	(1-Normal; 2-Abnormal)	P. 3
EARS:	[ ]	(1-Normal; 2-Abnormal)	P. 4
MOUTH/THROAT:	[ ]	(1-Normal; 2-Abnormal)	P. 4
CHEST:	[ ]	(1-Normal; 2-Abnormal)	P. 5,6,7
HEART:	[ ]	(1-Normal; 2-Abnormal)	P. 8
ABDOMEN:	[ ]	(1-Normal; 2-Abnormal)	P. 9,10

IF ANY OF THESE IS 2, THEN ADD APPROPRIATE PAGE(S) DETAILING ABNORMALITY(IES) FOR THE RELEVANT BODY REGION.

Figure III-36. Daily Medical Report Prepared by Physician Assistant/Nurse Practitioner.

Table III-27

The Number of Subjects Reporting Various Problems Prior to the Stated Energy Level.

(Total Count is the number of questionnaires reviewed. Some subjects may have filled out more than one questionnaire before a stated energy level.)

Energy Level	1	2	3	4	5	6	7	8	9	10
Total Count	33	32	30	29	28	27	35	19	18	9
Nose	0	0	0	0	0	0	0	0	0	0
Mouth/ Throat	3	1	3	2	1	3	1	1	0	0
Eyes	0	0	0	0	0	0	0	0	0	0
Sinuses	0	0	0	0	1	0	0	0	0	0
Ears	2	0	3	0	0	0	0	0	0	0
Chest	0	0	0	0	0	0	0	0	0	0
Heart	0	0	0	0	0	0	0	0	0	0
Abdomen	0	0	0	0	1	0	0	0	1	0

IV. DISCUSSION

A. FIRING FROM A BUNKER SIMULATOR

1. Auditory

With no auditory failures out of 59 subjects, clearly, the RACAL® muff, even if it does not make a good seal, can adequately protect its wearer up to the nonauditory limits of this type of reverberant blast wave. These limits, measured at the chest, were a peak of 48 kPa for one shot and 44 kPa for three shots. This resulted in typical exposures at the ear of 184 dB for one shot and 182.5 dB for three shots. The lack of an increase in TTS with increasing acoustical energy further supports the protective performance of the RACAL® muff.

However, it is essential to remember that the current study addressed only one type of reverberant waveform. For example, the waveform from firing from an enclosure is composed of low-frequency waves. These would not have a tendency to pull the muff away from the head. The reverberant waveform from the muzzle break of an M109 with the rear door open tends to produce a long negative phase. This long negative phase may pull the muff away from the head, providing much less protection while the higher sound frequencies are still decaying inside the crews' compartment.

2. Nonauditory

There were no nonauditory nor medical concerns from the blast exposures. The subjects accepted the exposures at the nonauditory limits for the reverberant waveform better than the exposures at the nonauditory limits of the freefield waveforms. Although there was a strong 50-60 Hz component to the waveform, none of the subjects complained about their chest vibrating although the resonant frequency of the chest should be in this 50-60 Hz range. The impulse must decay too quickly to set up a significant vibration. This is very different from the experience of steady sounds 25 to 30 dB lower. In this case, subjects exposed to such levels could not tolerate the sound (Sharpe et al., 1995).

The negative results of the PAB and hemoguaiac tests further attest to the acceptability of exposing soldiers to blast with a waveform similar to the one used in this simulation.

B. NONLINEAR PLUG STUDY

1. Auditory

a. Rucker Plug

We did not expect the three early failures of the Fort Rucker-designed nonlinear plug and, certainly, they raised a concern about the usefulness of this plug to the Army. It did work well with some subjects as nine subjects passed condition 6/12 (12 shots at 190 dB peak) without a problem. After condition 6/12, elective failures trimmed the number of the remaining subjects. Nevertheless, four subjects successfully passed condition 6/100. While the nonlinear plug did work for some subjects, it may be that the plug goes nonlinear at levels too high to protect the more sensitive individuals. It may also be that the triple-flange plug did not attain a good seal on all subjects exposed. The problem of attaining a good seal was not recognized until the French No. 1 plug was used.

Figure IV-1 is a plot of the results of these 13 subjects against the results of the perforated plug done in June 1993. The Rucker Plug was an improvement, but not much of one, over the perforated plug. For this reason, a request to use a more effective plug for the next group of subjects was made to the Institutional Review Board. They approved an addendum to the protocol to use a plug with a special filter designed by the researchers at the Institute Saint-Louis in France. This addendum was sent and subsequently approved by the Office of Deputy Chief of Staff for Regulatory Compliance and Quality Human Use Review and Regulatory Affairs Division on September 8, 1995.

b. French No. 1 Plug

After resolving the fitting problems that caused the early conditional failures on three of the subjects, the French No. 1 Plug appears to provide better protection than either the Perforated Plug or the Rucker Plug. Other than the one early failure at condition 3/6 (six shots at 181-dB peak level), the French No. 1 Plug protected the remaining subjects until condition 6/12 (12 shots at 190-dB peak level). There was another failure at condition 6/12. As will be discussed later, the fit of the plug of this early failure may not have been as good as it should have been.

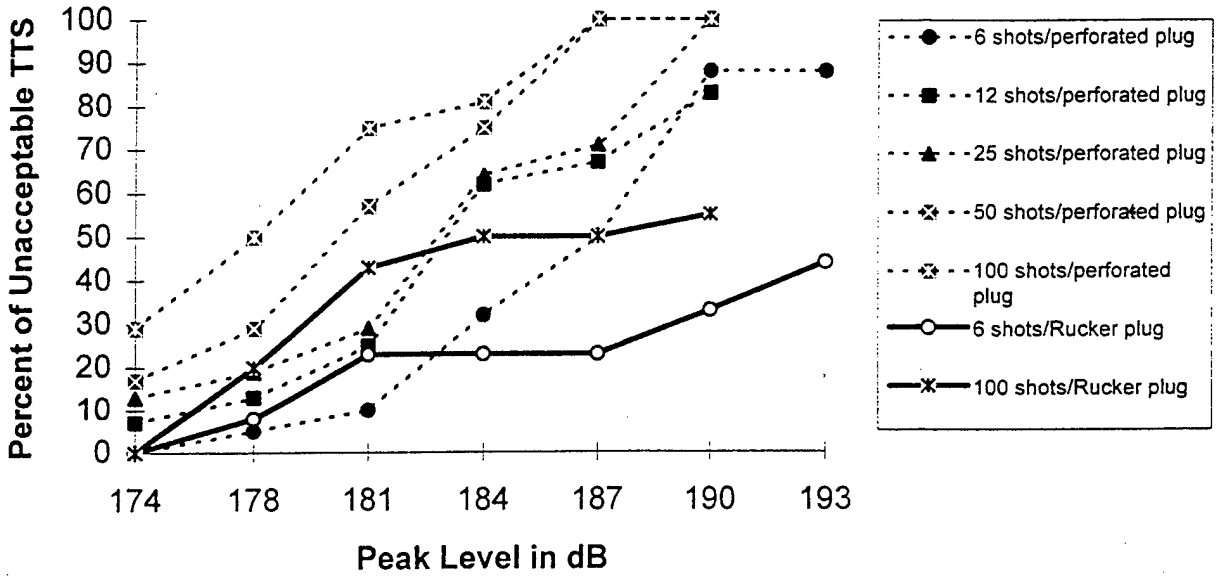


Figure IV-1. Comparison of Unacceptable TTS vs. Peak Level for Perforated Plug and Rucker Plug.

Finally, there was the conditional failure at Level 6/50. With all of these failures, TTS recovered normally. The summary of percent failed is shown in Figure IV-2. The results support the notion that the French No. 1 Plug does provide more protection than the nonlinear plug used for preceding groups. In addition, the curves of percent unacceptable TTS are starting to approach the results of the modified muffs. Figure IV-3 shows the percent unacceptable TTS for each of the four hearing protectors used. However, not enough subjects have been exposed with the different plug types to make any positive conclusions except to say that (1) clearly, the perforated plug is unlikely to be a useful solution and (2) it is questionable whether any more effort should be given to the nonlinear plug designed at Fort Rucker. One might argue that the early failure of the Rucker Plug was due to fitting. While this issue cannot really be resolved without more testing, the insertion loss data using the ISL head argues for the French No. 1 Plug. Regardless of which nonlinear plug is better, proper fitting of the triple-flange plug is essential.

Our experience with developing a more sophisticated method for checking for leaks is pertinent. When we started to block the hole at the stem of the French No. 1 Plug with an insulated wire of the same diameter of the hole, the first question that arose was how much of an increase of attenuation was necessary to ensure a good fit? We thought that an average increase of 5 dB might be adequate to show a seal around at least one flange. The exposure of subject 2076 changed our minds. This subject's audiometric failure was early in our learning curve about ensuring a proper fit. With this subject, the increase of attenuation was only 6 dB at 250 Hz, 2 dB at 500 Hz, and 5 dB at 4000 Hz. This was an improvement over his first try that day, but in retrospect, may not have been enough. Because of this subject, the criterion of any increase of attenuation of at least 10 dB at one of three frequencies (250, 500, and 4000 Hz) and 5 dB at the other two frequencies (10,5,5 criterion) was adopted. A summary of attenuation increases by blocking the hole at the stem of the French No. 1 Plug is shown in Table IV-1. The average attenuation change for 75 trials was 16 dB for 250 Hz,14 dB for 500 Hz, and 17 dB for

Table IV-1

The Average Hearing Threshold Level for 75 Trials for Subjects Wearing the French No. 1 Plug With and Without the Wire Insert That Blocked the Hole in the Stem of the Plug

French Plug No. 1	4000 Hz	500 Hz	250 Hz
Without Insert:			
Average	10.72	2.53	6.39
S.D.	6.62	6.32	6.38
With Insert:			
Average	26.91	16.62	23.66
S.D.	7.76	6.38	6.56
Average of Difference	16.19	14.09	17.27
S.D.	5.76	5.88	8.11

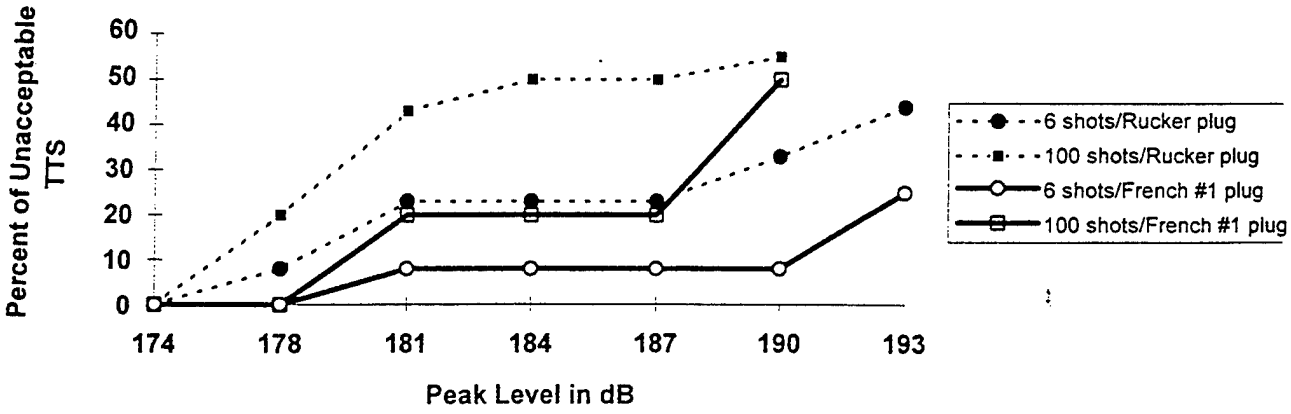


Figure IV-2. Comparison of Rucker Plug to French No. 1 Plug with Respect to Percent Unacceptable TTS vs. Peak Level.

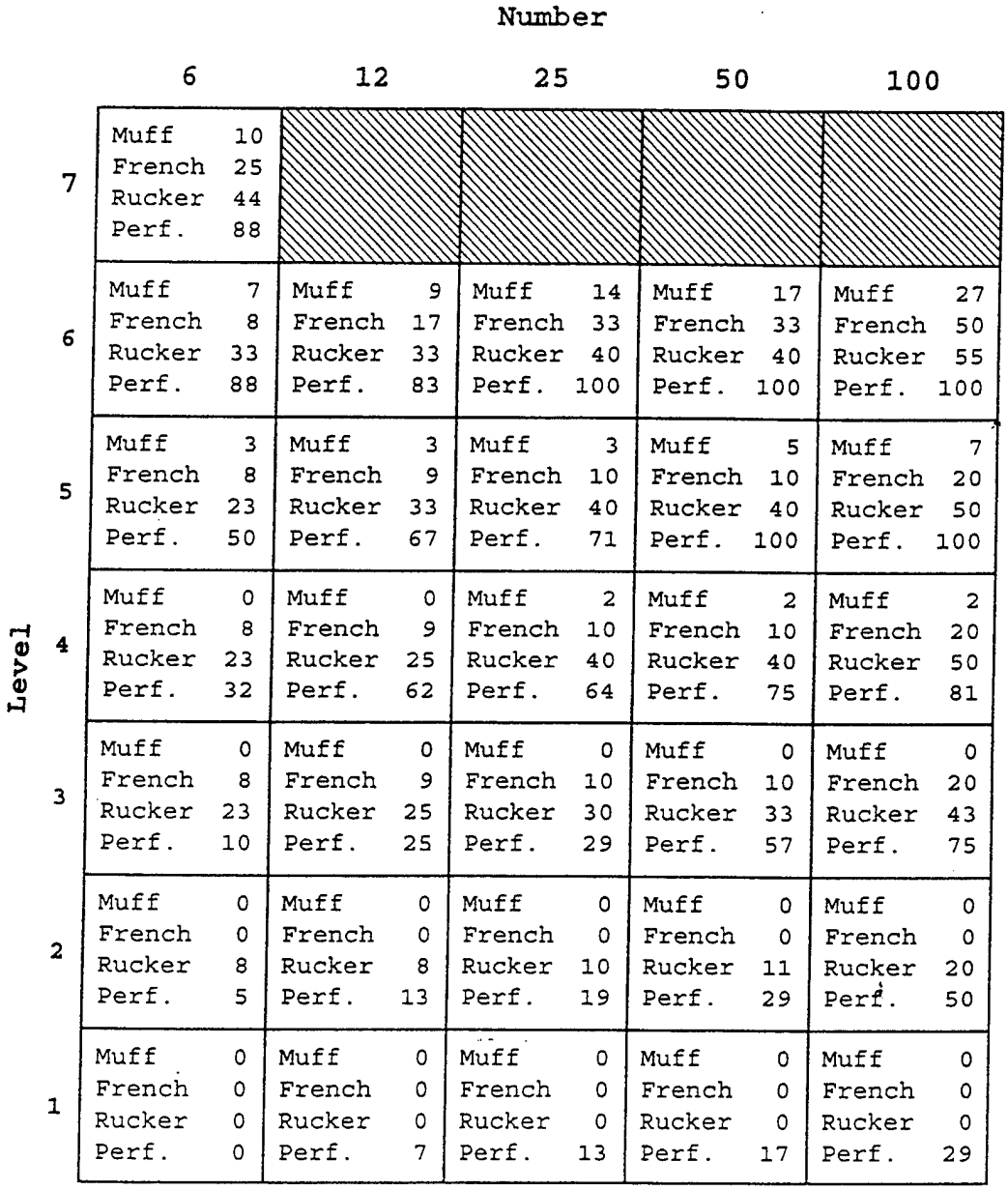


Figure IV-3. Percent Unacceptable TTS for the Modified Muff (68 Subjects), French No. 1 Plug (14 Subjects), Rucker Plug (13 Subjects) and Perforated Plug (19 Subjects).

4000 Hz. Thus, the 10,5,5 criterion was met by most subjects. However, this scheme is certainly not optimum. Table IV-1 lists the number of times each subject's plug (starting 2 October) either had to be repositioned or leanced and then reinserted. Ten of the fourteen subjects had trouble at one time or another. One improvement would be to do the audiometric baselines with the hole in the end of the plug blocked. Then, unblock the plug and do several audiometric frequencies looking for reduced attenuation, thus, checking for any blockage due to ear wax.

Another completely different approach would be simply to train the subjects to test the fit as they would have to in the field. If they then do not attain a good seal, so be it. Eventually, this is what we will have to predict in any case.

With respect to fitting, the experience of subject 2055 is also useful. This subject had to struggle to attain a seal with the ultrafit plug. When he did attain a seal, he stated that he believed that the blasts could loosen the plug such that he would lose the seal. When he first believed that he lost a seal (at Level 6/12), the PI immediately brought him off the pad for his safety. For the subsequent conditions, he was told he should check for a leak by placing his finger over the end of the plug (covering the hole) and checking for a change of attenuation of the PI's voice. If there was no or minimal change in the PI's voice level, he was to refit the plug and try again until the desired attenuation occurred, inferring a good seal. If he still did not attain a seal, he was to come off the pad before the next shot. During the 25- and 50-shot series, he had to readjust the plug twice. During the 100-shot series at Level 6, he readjusted his plug several times. In addition, his right ear started ringing. This interfered with his readjustment procedures and he became unsure if he were obtaining a good seal or not. After shot 44, he elected to come off the pad because of his concern that not attaining a good seal might be causing him a TTS. His 2-minute audiogram did not show any TTS. This subject demonstrated several issues to consider. First, if left to his own choice, he would have undoubtedly selected a solid foam plug such as an E.A.R.®. Second, the fact that he passed condition 6/50 essentially twice (6/44 of the 100-shot sequence) without TTS shows the usefulness of self fitting the plug and checking for a change in attenuation by covering the hole in the stem. Third, the early conditional failure at Level 1 undoubtedly was due to a poor seal. With a

Table IV-1

Summary of the Number of Additional Trials Needed to Properly Fit the French No. 1 Plug

Subject No.	Date	Level No./ Shot No.	No. Of Times Refitted	Procedure
2053	10-16-95	6/6	3	Repositioned
2055	10-05-95	1/12	1	Cleaned wax
	10-06-95	4/6	5	Cleaned wax
	10-10-95	3/12	2	Cleaned wax
	10-12-95	5/6	1	Cleaned wax
	10-16-95	6/6	4	Cleaned wax
	10-23-95	6/9	2	Cleaned wax
	10-24-95	6/25	1	Cleaned wax
	10-25-95	6/50	2	Cleaned wax
	10-26-95	6/44	2	Cleaned wax
2056	10-02-95	2/6	1	Cleaned wax
	10-03-95	3/6	1	Repositioned
	10-12-95	5/6	1	Repositioned
	10-23-95	6/12	1	Repositioned
2062	10-02-95	5/6	1	Cleaned wax
	10-26-95	6/12	1	Repositioned
2065	10-11-95	6/25	1	Repositioned
	10-23-95	0/12	1	Cleaned wax
	10-26-95	2/6	3	Cleaned wax and Repositioned
2066	10-04-95	3/6	1	Repositioned
2072	10-03-95	5/6	1	Cleaned wax
	10-05-95	6/12	1	Cleaned wax
	10-12-95	5/6	1	Cleaned wax
	10-23-95	6/12	1	Cleaned wax
2073	10-12-95	5/6	3	Cleaned wax
	10-24-95	6/25	1	Repositioned
2076	10-03-95	2/6	1	Repositioned
	10-05-95	3/6	1	Cleaned wax
2086	10-20-95	7/6	1	Repositioned
Total No. of Times Cleaned and/or Repositioned			46	

proper seal the French No. 1 Plug adequately protected this subject.

Besides subject 2076, three other subjects had a TTS with the French No. 1 Plug. There is the possibility that their TTS's could have been due to a loss of a good seal. Nevertheless, since there is no way to know for certain, these TTS's must be assessed against the French No. 1 Plug as used in its present configuration (see Fig. I-9). With the French No. 1 filter in the front end of the plug, the first one or two of the flanges are slightly distorted. It has been suggested that a better seal may be attained if the French No. 1 filter is placed in the stem of the plug. Before more subjects are exposed, the P.I. recommends this change.

The significant correlations of TTS vs. energy level at 500 Hz and 1000 Hz are of some concern. Until this plug we have never had TTS correlate with energy level. It may be that the small orifice in the French No. 1 Plug allows a more classical growth of TTS with level. Thus, the typical "none" or "a lot" of TTS seen for the muff as well for the Rucker Plug may not be predominating with the French No. 1 Plug. In any event, more subjects using the French No. 1 Plugs are definitely needed to evaluate this plug further.

c. E.A.R.® Foam Plug, Right Ear

The ten subjects that have used this plug have been exposed at various parts of the matrix. However, most exposures were in the middle energy levels. This is to be expected as five of the subjects were those who at some point in the matrix had an audiometric failure with first-level hearing protection. Therefore, second-level hearing protection was started. The other five subjects were started at Level 5 because the matrix was virtually closed out to first-level hearing protection when protection was the perforated plug.

It is noteworthy that there has not been an auditory failure with the E.A.R.® foam plug, especially, considering that 50 percent of the subjects were already shown to be more sensitive to impulse noise.

In addition, regression analysis has not shown any effect. It is unfortunate that not enough subjects have been exposed to be confident that the E.A.R.® foam plug will protect at least 95 percent of the population. Nevertheless, the E.A.R.® foam plug looks very promising.

d. E.A.R.® Foam Plug, Left Ear

Because the E.A.R.® foam plug was always used by itself in the left ear for the perforated plug study and for both of the nonlinear plug studies, data from more than 46 subjects are available. In addition, the data of subjects that used second-level hearing protection in their right ear can also be used. It is true that the head shielded the left ear somewhat and that the left ear audiogram was started 5.5 minutes after the right ear audiogram. However, there was never an auditory failure in the left ear. There was no correlation between TTS and exposure energy. The typical TTS seen in the right ear did not recover in 5.5 minutes and, thus, would have still been easily seen had the audiometry been delayed 5.5 minutes. One can only conclude that up to now, the E.A.R.® foam plug has been completely effective. The only question is to what level has it been effective? Using the ISL head, the shielding of the head reduced the peak level by 6 dB. The average A-weighted energy drop for the 3-m waveform was 8 dB. The average P-weighted energy drop was also 8 dB. Depending on which correction factor one would prefer, one only has to reduce the matrix by 6 to 8 dB. We would like to suggest 6 dB as a reasonable estimate since the use of peak level is more common.

Since 31 subjects completed matrix condition 6/12 (or 12 shots at 190 dB) we can say with 95% confidence that less than 10% of the population should have unacceptable TTS (25 dB) with the E.A.R.® foam plug for the exposure of 184 dB (190 dB -6 dB) for 12 shots. The E.A.R.® foam plug probably does better than this, but at least the left ear data does anchor this point on the matrix with enough subjects to have some statistical significance. Combined with the 10 subjects' right-ear data, the E.A.R.® foam plug is certainly likely to perform as well as the unmodified RACAL® muff.

The adequacy of the E.A.R.® foam plug for levels up to 184 dB is also backed up by studies using actual weapons. Patterson (1985) demonstrated this for the M198 155-mm towed howitzer. Carter

(1989) demonstrated this for Australian artillerymen firing the L118/119 105-mm howitzer.

2. Nonauditory

Except for the one subject that had the headaches, which seemed to be due to the pressure waves entering his sinuses, there were no significant nonauditory problems. There have been 87 subjects that were previously exposed at this distance without a problem. The problem of this one subject, therefore, if indeed real, is not considered significant.

C. SUBJECTS ACCEPTANCE OF THE NONLINEAR PLUGS

The subjects generally did not accept the nonlinear plug as well as the RACAL® muff. However, they accepted the nonlinear plug much better than the perforated plug. This shows up in two ways. First, with the RACAL® muff, 38 of 60 (63%) subjects thought Level 7 of the 3-m distance was acceptable. Similarly, 31 of 60 (52%) thought condition 6/100 was acceptable. With the Rucker Plug, only 1 of 7 (14%) thought Level 7, as well as condition 6/100, acceptable. With the French No. 1 Plug, only 4 of 13 (31%) thought Level 7 acceptable. However, 7 of 13 (54%) thought condition 6/100 would be acceptable.

Another way to illustrate this acceptance, or lack thereof, is to look at the number of elective failures, especially to Level 7. With the RACAL® muff, 46 of 58 (79%) elected to go to Level 7. With the Rucker Plug, 5 of 8 (63%) elected to go to Level 7. With the French No. 1 Plug, only 3 of 11 (27%) elected to go to Level 7.

Although the French No. 1 Plug did as well as the RACAL® muff at condition 6/100 (as shown on the questionnaire), the subjects were not nearly as comfortable to being exposed to Level 7. The hole through the French No. 1 filter gave some of them a feeling that their ears were not being protected. In spite of the PI assuring the subjects that the plugs did attenuate more as the level was increased, when one subject had a TTS, some subjects lost confidence in the plug. The same can be said for the Rucker Plug. Although 5 of 8 subjects were willing to be exposed to Level 7, only one subject thought that level was an acceptable exposure.

In summary, the use of a nonlinear plug with a hole in it will probably not be accepted by every individual. Some percentage of the population will opt for a solid plug without an orifice.

D. PRE- AND POST AUDIOGRAMS

With respect to how well did the E.A.R.® foam plugs protect the left ear, the key issue is the significant positive differences in the left ear at 4, 6, and 8 kHz between the post experiment-preexperiment audiograms as done by Lovelace is how well did the E.A.R.® foam plugs protect the left ear? Because of the implications of these differences, every effort was made to see if there was an indication that the left ear was not being adequately protected. There are few arguments, supporting the fact that the E.A.R.® foam plug did provide adequate protection. First, the regression analysis done on the left ear did not show an effect that increased with level. Second, the ten subjects that used the E.A.R.® foam plug on the right ear did not show any effect even though this exposure was more intense. Third, the last audiograms that were taken using the BOP system did not show any change. Finally, the audioscan audiometry showed an improvement in hearing at these frequencies. Thus, we believe the E.A.R.® foam plug, when properly fitted, as was ensured by the BOP subjects through a REAT, provides adequate protection for the 3-m distance type waveform up to levels of 184 dB.

E. MEDICAL DATA

Other than some complaints of headaches, there were no indications of any medical problems occurring. As the study progressed, the subjects reported fewer medical complaints on their preexposure questionnaires. The spirometry data did not significantly correlate with exposure level.

These results were consistent with the results of subjects previously exposed at this distance with the RACAL® muffs.

F. PERFORMANCE ASSESSMENT BATTERY (PAB) TESTS

The subjects enjoyed doing the 3-minute PAB test and, generally, took pride in being able to do better as the study progressed. It was surprising to see how fast some subjects could do the math task.

The PAB results showed no change in performance due to the blast exposure.

Unfortunately, the post exposure PAB was given after the 20-minute audiogram, or approximately 35-45 minutes post exposure. Thus, there is always the open question as to an effect if there were time to do the PAB immediately post exposure. However, the audiometric testing is within 2 minutes of the exposure. The subjects handled this task just fine.

SECTION V. CONCLUSIONS

A. FIRING FROM A BUNKER SIMULATOR

A reverberant wave environment was established that simulated the waveform expected as the result of shooting a rocket-type weapon out of an enclosure. Using the nonauditory subthreshold levels (no-injury levels, 48 kPa for one shot and 44 kPa for three shots at the chest) established for sheep, this study established that the auditory system can be adequately protected at these nonauditory limits by a muff-type protector, even if the fit is not perfect. The lack of an audiometric failure in any of the 59 subjects completing the study means that the RACAL® muff should protect 95% of the population with a 95% confidence factor from TTS of more than 25 dB when exposed to a peak at the ear of 184 dB for one shot or a peak of 182.5 dB for three shots.

Performance assessment battery tests also showed a lack of effect. No medical problems occurred. In addition, most of the human volunteers thought the exposures were quite tolerable. Thus, nonauditory considerations set the upper limit of safe exposure of this type of reverberant waveform.

In summary, of the 64 subjects entering the study, no known significant permanent shift in hearing occurred in any subject. As a group, the mean post hearing level of the subjects was better at all frequencies than the mean preexposure levels. There were no injuries to any subject. The exit questionnaires show that more than 91% of the subjects thought the study was worthwhile, more than 96% of the subjects said they would recommend the study to others. Overall, we feel the objectives of the study were met and the study was a success.

B. NONLINEAR EARPLUG STUDY

The results from five months of testing of 27 subjects using nonlinear ear plugs have shown that, unlike the RACAL® muff, the soldiers' hearing could not be safeguarded up to impulse exposure conditions that are at the threshold of nonauditory injury.

Like the perforated plug of the previous study, the nonlinear plug designed at Ft Rucker was inadequate. Perhaps with additional

subjects, the plug might be safe for shots at 175 dB (11 kPa) and below. However, like the perforated plug, they made it difficult to understand speech in windy conditions. Thus, there is no valid reason to use them.

The nonlinear plug that used a special filter designed in France performed better and may be a satisfactory solution. However, not enough subjects were exposed to provide a definitive answer.

The E.A.R.® foam plug does seem to provide adequate protection, although not enough subjects have worn this plug in the right ear to be statistically confident at the nonauditory limits. The left ear data does approach statistical confidence. If we consider that there is only a couple of decibels difference in the peak level exposure between the left and right ear, the E.A.R.® foam plug should be as effective as the RACAL® muff. The RACAL® muff protected 95% of the subjects to 187 dB for 6 and 12 shots and to 184 dB for 25 to 100 shots (Johnson 1994).

In summary, 27 subjects entered the study. We believe that no significant permanent shift in hearing occurred in any subject. There were no major injuries to any subject. The exit questionnaires show that more than 96 percent of the subjects thought the study was worthwhile, 100 percent said they were glad they volunteered, and 85 percent of the subjects said they would recommend the study to others. The lack of a sufficient number of subjects meant that not all the objectives of the study were achieved. Otherwise, the study was successful.

SECTION VI. RECOMMENDATIONS

1. A. FIRING FROM A BUNKER SIMULATOR

For reverberant waveforms, similar to the ones we used in our simulation, the RACAL® muff is recommended for use up to the nonauditory limits (~48 kPa or 185 dB at the chest). Because of the almost complete lack of auditory effects, the fact that the levels at the ear may be 1 or 2 dB higher should be ignored.

Because we have no data with respect to plugs, we cannot recommend plugs for this type of reverberant exposure.

B. FREEFIELD WAVEFORM EXPOSURES

In our previous report (Johnson et al., 1994) we recommended the maximum planned peak SPL for freefield waveforms with durations of 0.8 to 3 ms that should be allowed for any human exposures with adequate hearing protection (such as the RACAL® muff or the E.A.R.® foam plug) should be limited to 188 dB. For a number of exposures greater than 25, auditory considerations dictate that these levels may need to be reduced dependent on the percent of the population to be protected. An occasional exceedance (less than 10% of the time) of this 188-dB level by less than 3 dB should be acceptable.

Based on this current study, this modification to this recommendation would be to state that the only proven adequate protection is the RACAL® muff or the E.A.R.® foam protection. Based on our problems with fitting the triple-flange plugs, we are not sure that any plug that cannot obtain a good seal in a very high percentage of the population should be used for the very high level impulse noises.

We cannot recommend general use of the two nonlinear plugs we tested. It is possible that the French No. 1 Plug, modified to put the filter in the stem instead of the front, might be acceptable for some special situations. More testing, however, is needed to demonstrate this.

SECTION VII

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APPENDIX A. TYPICAL VOLUNTEER CONSENT FORM AND REGISTRY DATA SHEET

1. FIRING FROM BUNKER SIMULATOR STUDY

2. NONLINEAR EARPLUG STUDY

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG.

PRIVACY ACT OF 1974

Authority:	10 USC 3013, 44 USC 3101, and 10 USC 1071-1087
Principal Purpose:	To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.
Routine Uses:	The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State, and local agencies.
Disclosure:	The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A – VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____ SSN _____,

having full capacity to consent and having attained my _____ birthday, do hereby volunteer to participate in Direct Determination of Exposure Limits for Intensive Reverberant Impulse Noise

(Research study)

under the direction of Daniel L. Johnson, Ph.D., 505-846-4252 or -4253, DSN: 246-4252

conducted at EG&G MSI, Kirtland Air Force Base, New Mexico

(Name of Institution)

The implications of my voluntary participation; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

_____

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights or study-related injury, I may contact Command Judge Advocate, U.S. Army Medical Research, Development, Acquisition and Logistics (USAMRDAL) Command,

at SGRD-JA, Fort Detrick, MD 21702-5012, DSN: 343-2065; 301-619-2065

(Name, Address and Phone number – include Area Code)

I understand that I may at any time during the course of the study revoke my consent and withdraw from the study without further penalty or loss of benefits; however I may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

APPENDIX A - Atch 1
Firing from a Bunker
Simulator Study

PART B – TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: *(Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25.)*

See attached Volunteer Consent Form

I do ☐ do not ☐ *(check one & initial)* consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER	DATE

PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

The objective of this study is to determine the safe limits of occupational exposure to impulse noise similar to the noise produced by anti-armor weapons fired from an enclosure while hearing protection is used. This study is being carried out at Kirtland Air Force Base, NM, under contract to the US Army Medical Research, Development, Acquistion and Logistics (USAMRDAL) Command. Researchers from the Walter Reed Army Institute of Research (WRAIR), Washington, D.C., and the US Army Aeromedical Research Laboratory (USAARL), Ft Rucker, AL, have designed the project and are actively involved in overseeing this research conducted by EG&G Special Projects. The project has been approved by the Army 's Surgeon General.

There is much evidence from human and animal studies that the protected ear is not as sensitive as was once thought to the blast overpressure (BOP) made by large caliber weapons. We now have a much better idea of the level of BOP needed to injure the lungs or other parts of the body and it is considerably above any current exposure limits. The purpose of this study is to determine precisely how much impulse noise can be safely tolerated. The results of this study will be used to help set limits on weapon noise and will have an important influence on soldier safety. **There will be no medical benefit to you personally as a result of your participation in this study other than the possibility of discovering an unrelated, underlying disease as a result of the medical examinations during this study.** However, your participation could help prevent hearing loss in the future in other military personnel.

Your participation in the study will last up to six weeks. You and up to thirteen other volunteers will be on TDY status at Kirtland Air Force Base, NM. You will be permitted leave at the end of training prior to reporting to Kirtland AFB. Visits by family members will be permitted; however, family housing will not be provided. You will work only on weekdays unless uncontrollable weather or technical problems limit the number of weekday tests. You will be provided with all necessary helmets and ear protection and are expected to wear the Battle Dress Uniform.

The test will be conducted in a chamber on an open concrete pad and the source of BOP will be an explosive charge detonated outside the chamber. The blast will be allowed to enter the chamber through an 8-inch diameter tube. This tube will simulate the launch tube of an anti-armor weapon. The blast arriving inside the chamber will simulate the back blast of such a weapon. No actual weapons will be used. You will be instructed to sit at a given distance from the opening of the blast tube. You will begin your exposures wearing ear muffs and the first test condition will be a single

Initials: Volunteer_____ Date_____ Witness_____ Date_____

exposure to a BOP that is below the presently accepted safe limit. You will be instructed in the proper use of the hearing protection. We will check your ear muffs (or ear plugs) each day and will not let you be exposed to the impulse noise if they are not fitted properly. The test ear will have either earplugs, ear muffs, or both. The non-test ear will always have plugs and sometimes both.

Before and after each day's exposure, you will have hearing tests performed. If you have any unusual sensations in your throat before or after a test, a doctor will examine it. The throat examination is done to detect any bruising and is explained in more detail below. In the hearing tests, we will be looking for small, temporary decreases in your hearing sensitivity. This will be like the temporary hearing loss, the "cotton in the ears" sensation, we have all commonly experienced after operating loud machinery or going to a loud rock concert. If we detect a certain level of loss of hearing sensitivity (a level that you may not be able to notice) during the tests with ear muffs and/or ear plugs, you will not be allowed to be exposed to any greater strength of BOP while you are wearing ear muffs and/or ear plugs. It is very likely that some, if not most, individuals will have at least one such temporary loss. It is possible that a few individuals will have several such events. If we observe any change in your hearing, even one that we don't consider critical, you will not be exposed again until your hearing has returned to normal.

There is a small risk of permanent hearing loss. The risk of permanent hearing injury resulting from a few incidents of temporary sensitivity loss is not precisely known. However, a panel of NATO scientists and a panel of US hearing specialists have reviewed this question and have concluded that, while such a possibility exists, the risk is small given the design of this study. In order to avoid uncontrolled noise exposures which could be hazardous to your hearing and could invalidate the test, you must agree to avoid noisy environments such as shooting guns, hunting, lawn mowing, motorcycle riding, power boating, use of power tools, chain saws, routers, etc., and loud music (rock concerts, discos, and loud stereo equipment) for the duration of your participation.

A check for hearing change (and, if necessary, a throat examination) will be done after each exposure and before the next test condition. You will be tested for many possible combinations of strength and number of blasts up to certain limits. The maximum number of blasts that you will be exposed to on any given day is 3. The maximum strength has been determined by the risk of nonauditory bruising as outlined below. After you have completed the tests using ear muffs, you may start additional testing using ear plugs instead of muffs. Once you have been tested for the pertinent conditions using ear plugs, you may be tested using both plugs and muffs at the same time. You will not be exposed to more than 30 different conditions. The very first exposure condition will not be more than the maximum level allowed by the current policy of The

Initials: Volunteer_____ Date_____ Witness_____ Date_____

Army Surgeon General (MIL-STD-1474B). Some following conditions will exceed what is now allowed in training.

In addition to conventional audiometry, we will be conducting other tests of your hearing using specialized instrument, e.g.: a swept frequency audiometer to test hearing, a tympanometer to test middle ear, and an otoacoustic emission tester to measure sounds normally coming out of your ears. We will also ask you to complete a synthetic work task to test your mental alertness. In addition, several questionnaires will be used to determine your opinions about the study and the blast exposures.

Before each exposure, a medical evaluation will be accomplished by the on site physician assistant/nurse practitioner. This will include a medical self-history form which you will complete and a brief physical examination including: weight, temperature, pulse, respiratory rate, blood pressure, otoscopic examination of the ears, nose and throat examination, examination of the chest and heart and abdominal palpation (pressing on the abdomen). You will also be given a spirometry test before and after each exposure. This test involves blowing as hard as possible into a test machine which measures the flow rates.

In addition to affecting your hearing, there is a very small chance that the BOP may cause minor, reversible injury (like bruising) to your larynx (voice box) and trachea (windpipe), your lungs, or your stomach and intestines. There is a great deal of information which indicates that the risk of injury to these organ systems is very small. Even if injury does occur, it will not be serious and will heal quickly with no lasting effects. Injuries occurring to your lungs and windpipe when you have a cold or laryngitis are much more serious than those expected during this study. **Other potential sources of risk, although very small, include accidental detonation during explosives handling, flying debris generated by the blasts, noxious gases, heat and cold stresses, and physical examination procedures.**

We have set an absolute maximum on the strength of the blast based on the lowest level of blast which will cause minor, temporary injury in a small percentage of exposed large animals. Using hundreds of animals (sheep), we have carefully determined what strength of blast wave in this chamber, when given 1 or 3 times, causes a barely detectable bruising in a small percentage of tested animals. This level will be the absolute limit for your exposures.

To examine your throat for evidence of bruising, we must get a look behind and below the base of your tongue. This is done by using a small flexible viewing tube into the throat. This procedure may cause you to gag and an anesthetic (numbing medicine) may be necessary. You may experience a nose bleed or retching. This examination will be performed only by a trained physician. Your

Initials: Volunteer_____ Date_____ Witness_____ Date_____

throat will be examined before any blast exposures and after as many as four of the more intense exposures, at any time the daily review of your medical status indicates and at the end of your participation.

To qualify for participation in the study you must be a male on military active duty with less than 5 years of service. You will be disqualified if you have a significant hearing loss or if you show any abnormalities during a physical exam. Final participants will be selected by the recruiting team from all qualified volunteers. If you are selected as a participant, you will receive a medical examination in Albuquerque, NM to determine whether or not you have any medical conditions which might increase your chances of being injured, however slightly. In addition to demonstrating normal hearing, you will have a standard chest x-ray. A breathing test will be done where you will breathe in as much air as you can and blow into a machine as forcefully as possible. We will analyze a blood sample (approximately 5 to 7 teaspoonfuls) and a urine sample and we will check your heart with an electrocardiogram. In addition, we will ask you to supply us with a small sample of stool (bowel movement) which we will check for blood. All of these tests are simple and easy to perform and all will be done before you begin the study. The drawing of the blood sample may cause discomfort, bruising, or swelling. If abnormalities are found on the screening tests, you will not be allowed to participate in the study and you will be referred to an appropriate medical facility for evaluation. Information concerning previously undetected, preexisting medical conditions which is developed during your participation in this study could result in your being involuntarily released from active duty. You may not participate in this study if you have a history of allergy to local anesthetics (like Novocaine) or a history of respiratory (breathing) problems, allergic rhinitis (hay fever), sinusitis (inflammation of the nasal passages), or emphysema (a lung disease).

During the time you are present in Albuquerque you will be under the supervision of the contract investigators at KAFB. They will arrange for pick-up and drop-off at the airport in Albuquerque and for your transportation needs while in Albuquerque. You will be expected to maintain an appropriate level of physical fitness during the test. At all times you must remember that we are guests at the KAFB in Albuquerque, NM. You are expected to conduct yourselves as soldiers and good citizens. Any misbehavior will result in your being sent immediately to your permanent duty station. Serious misconduct will lead to prosecution under the Uniform Code of Military Justice.

The results of this study will be used in deciding how to protect the hearing of the Army crews who will fire anti-armor systems from enclosures. Your participation is entirely voluntary and you are free to revoke this consent and withdraw from the study at any time. If you withdraw, you will travel immediately to your next duty assignment. Your participation in this study is completely

Initials: Volunteer_____ Date_____ Witness_____ Date_____

voluntary. Your decision to withdraw at any point from the study will involve no penalty or loss of benefits to which you are otherwise entitled and will in no way prejudice your service record.

There will be a physician or a physician's assistant available during all phases of the study should you have any questions regarding your health and participation in this study. You will be provided medical care for physical illness or injury while participating in this research at no cost to you. In case of a medical emergency at the test site, you will be transported by ambulance to Kirtland Air Force Base Hospital for follow-up and/or treatment. If you wish to leave the study, notify any of the investigators at KAFB or the medical monitor. We may end your participation in the project early if we think it is best for your health and safety.

The point of contact (POC) for explanation of rights as a research subject is: Command Judge Advocate, U.S. Army Medical Research, Development, Acquistion and Logistics (USAMRDAL) Command, SGRD-AJ, Fort Detrick, Frederick, MD. 21702-5012; DSN: 343-2065 or (301) 619-2065.

HANDLING OF DATA

All research data and medical information collected during your participation in this study will be used to achieve the objectives of the study and to help assure your safety and health during your participation. The research data resulting from this study will be presented in military and scientific presentations. It will be available for review and analysis by other scientists. During the conduct of this research we may take photographs, motion pictures, and/or video recordings of you. These may include sound recordings. This visual and acoustic information will be used in public presentations and published in scientific and/or technical reports resulting from the research. These presentations and reports are essential for conveying the scientific and technical aspects of the research to various interested groups. Confidentiality is not guaranteed. Information linked to you by name or other identifiers may be released without your express written permission including photographs, motion pictures and video tape. Complete confidentiality cannot be promised, particularly to military personnel, because information on your health may be required to be reported to appropriate medical or command authorities. During the course of your participation in this research project, you will be provided with any new information that develops that may relate to your willingness to continue to participate.

Initials: Volunteer_____ Date_____ Witness_____ Date_____

Before you sign this volunteer agreement, you must answer the attached questions to demonstrate your understanding of the information in this briefing.

You will be given a copy of the volunteer agreement after you have signed it. If you have any questions about your participation in this project, please call collect to one of the following:

Dr. James H. Patterson, Jr.
U.S. Army Aeromedical Research Laboratory
(205) 255-6821

MAJ John Ribera
U.S. Army Aeromedical Research Laboratory
(205) 255-6913

By signing this form I hereby acknowledge I have fully read and understand the contents. Any questions I might have had have been answered to my satisfaction. I am signing this form voluntarily. I further acknowledge I have received a copy of this form to keep.

Signature of Volunteer Date

Typed or printed name of Volunteer

Permanent Address

Signature of Witness Date

Typed or printed name of Witness

SIGNATURE OF PERSON OBTAINING CONSENT

I have counseled the above volunteer as to the nature of this research study, the risks involved, and the contents of this consent.

Signature of Person Obtaining Consent

Title Date

TESTS OF VOLUNTEER UNDERSTANDING OF RISKS

Circle all of the correct answers for each question. There may be one or more than one correct answer for each question. Base your answers on the information discussed in the Volunteer Consent Form that was read during the session:

1. When can you withdraw from this study?

   a. First week
   b. Second week
   c. Third week
   d. Anytime
   e. Never

2. Of the following injuries which are possible in this study?

   a. Bruising of internal organs such as the lungs, stomach, and intestines
   b. Broken bones
   c. Bruising of the voice box and windpipes
   d. None of the above

3. Of the following which are other minor sources of risk?

   a. Heat/cold injury
   b. Cancer
   c. Noxious (harmful) gases
   d. None of the above

4. Is there even a small chance of an injury from an accidental detonation during explosives handling or from flying debris generated by the blasts?

   a. Yes
   b. No

_____ _____

Signature Date

_____

SSAN

VOLUNTEER REGISTRY DATA SHEET

THIS FORM IS AFFECTED BY THE PRIVACY ACT OF 1974

1. AUTHORITY: 5 USC 301; 10 USC 1071-1090; 44 USC 3101; EO 9397

2. Principal and Routine Purposes: To document participation in research conducted or sponsored by the U.S. Army Medical Research and Development Command. Personal information will be used for identification and location of participants.

3. Mandatory or Voluntary Disclosure: The furnishing of the SSN is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your participation in the research study.

PART A-INVESTIGATOR INFORMATION

(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

1. Study NR: _____ 2. Protocol Title: Direct Determination of Exposure Limits for Intensive Reverberant Impulse Noise

3. Contractor (Laboratory/Institute Conducting Study): EG&G MSI

4. Study Period: From: 21/6/93 (DA/MO/YR) To: 20/11/98 (DA/MO/YR)

5. Principal/Other Investigator(s) Names(s)

6. Location/Laboratory

(1) JOHNSON, DANIEL L. (Last) (First) (MI) — Kirtland AFB, Albuquerque, NM

(2) _____ — _____/_____

(3) _____ — _____/_____

PART B-VOLUNTEER INFORMATION

(To Be Completed By Volunteer)

PLEASE PRINT, USING INK OR BALLPOINT PEN

7. SSN: ___/___/_____ 8. Name: _____ (Last) (First) (MI)

9. Sex: M__F__ 10. Date of Birth: __/__/__ 11. *MOS/Job Series: ___ 12. *Rank/Grade: ___

13. Permanent Home Address (Home of Record) or Study Location Address:

_____ (Street) (P O. Box/Apartment No.)

_____ (City) (Country) (State) (Zip Code)

(___) _____ (Perm Home Phone No)

14. *Local Address (If Different From Permanent Address):

_____ (Street) (P O. Box/Apartment No.)

_____ (City) (Country) (State) (Zip Code)

(___) _____ (Local Phone No)

15. *Military Unit: _____ Zip Code: _____

Organization: _____ Post: _____ Duty Phone No. (___) _____

USAMRDC Form 60-R Revised 1Apr 88 (Supersedes previous editions)

PART C-ADDITIONAL INFORMATION

(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

16. Location of Study:

17. Is Study Completed: Y___ N___

Did volunteer finish participation: Y___ N___ If YES, Date finished: ___/___/___
(DA/MO/YR)

If NO, Date withdrawn: ___/___/___ Reason withdrawn:
(DA/MO/YR)

18. Did Any Serious or Unexpected Adverse Incident or Reaction Occur: Y___N___ If YES, Explain:

19.*Volunteer Followup: _____

Purpose: _____

Date: ___/___/___ Was contact made: Y___N___ If No action taken, explain:
(DA/MO/YR)

20.*Hard Copy Records Retired: Place: _____ File NR: _____

21.*Product Information:

Product: _____

Manufacturer: _____

Lot NR: _____ Expiration Date: _____

NDA NR: _____ IND/IDE NR: _____

*Indicates that item may be left blank if information is unavailable or does not apply.
Entries must be made for all other items.

Consent for use of visual information collected during participation in "Direct Determination of Exposure Limits for Intense Reverberant Impulse Noise"

I hereby give my permission for the use of visual information collected in conjunction with the study entitled "Direct Determination of Exposure Limits for Intense Reverberant Impulse Noise," including photographs, motion pictures, and video recordings with sound tracks in which I may be recognizable for public presentations and publication in scientific and/or technical reports.

_____

Signature & Date

_____

Witness & Date

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG.

PRIVACY ACT OF 1974

Authority:	10 USC 3013, 44 USC 3101, and 10 USC 1071-1087
Principal Purpose:	To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.
Routine Uses:	The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State, and local agencies.
Disclosure:	The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A — VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____ SSN _____,

having full capacity to consent and having attained my _____ birthday, do hereby

volunteer to participate in Nonlinear Earplug Study
(Research Study)

under the direction of Daniel L. Johnson, Ph.D., 505-846-4252 /4253, DSN 246-4252/4253

conducted at EG&G MSI, Kirtland Air Force Base, New Mexico
(Name of Institution)

The implications of my voluntary participation; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

MAJ John Ribera

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights or study-related injury, I may contact Command Judge Advocate, U.S. Army Medical Research and Materiel Command, ATTN: MRMC-JA, Fort Detrick, MD 21702-5012

at DSn 343-2065, 301-619-2065
(Name, Address and Phone number – include Area Code)

I understand that I may at any time during the course of the study revoke my consent and withdraw from the study without further penalty or loss of benefits; however I may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: *(Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25.)*

See attached Volunteer Consent Form

I do ☐ do not ☐ *(check one & initial)* consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER	DATE
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS
	SIGNATURE OF WITNESS / DATE

The objective of this study is to determine the safe limits of occupational exposure to impulse noise characteristic of mortars and howitzers fired in the open. This study is being carried out at Kirtland Air Force Base, NM, under contract to the US Army Medical Research and Materiel Command (USAMRMC). Researchers from the Walter Reed Army Institute of Research (WRAIR), Washington, D.C., and the US Army Aeromedical Research Laboratory (USAARL), Ft. Rucker, AL, have designed the project and are actively involved in overseeing this research conducted by EG&G Management Systems, Inc. The project has been approved by the Army Surgeon General's Human Subjects Review Board.

There is much evidence from human and animal studies that the protected ear is not as sensitive as was once thought to the blast overpressure (BOP) made by large caliber weapons. We now have a much better idea of the level of BOP needed to injure the lungs or other parts of the body and it is considerably above any current exposure limits. The purpose of this study is to determine precisely how much impulse noise can be safely tolerated. The results of this study will be used to help set limits on weapon noise and will have an important influence on soldier safety. There will be no medical benefit to you personally as a result of your participation in this study other than the possibility of discovering an unrelated, underlying disease as a result of the medical examinations during this study. However, your participation could help prevent hearing loss in the future in other military personnel.

Your participation in the study will last up to six weeks. You and up to thirteen other volunteers will be on TDY status at Kirtland Air Force Base, NM. You will be permitted leave at the end of training prior to reporting to Kirtland AFB. Visits by family members will be permitted; however, family housing will not be provided. You will work only on weekdays unless uncontrollable weather or technical problems limit the number of weekday tests. You will be provided with all necessary helmets and ear protection and are expected to wear the Battle Dress Uniform.

The test will be conducted on an open concrete pad and the source of BOP will be an explosive charge detonated inside a large tube. The blast will escape at the end of the tube and will spread out to

where the subjects are seated, 5.5 to 7 ft from the opening of the blast tube. The blast arriving from the tube will simulate a blast such as that of a mortar or similar weapon. No actual weapons will be used. You will be instructed to sit at a given distance from the opening of the blast tube. You will begin your exposures wearing ear plugs and the first test condition will be an exposure to a BOP that is below the presently accepted safe limit. You will be instructed in the proper use of the hearing protection. We will check your ear plugs (or ear muffs) each day and we will not let you be exposed to the impulse noise if they are not fitted properly. The test ear will have either ear plugs, ear muffs, or both. The non-test ear will always have ear plugs and sometimes both.

Before and after each day's exposure, you will be asked to have hearing tests performed. If you have any unusual sensations in your throat, before or after a test, a doctor will examine it. The throat examination is done to detect any bruising and is explained in more detail below. In the hearing tests, we will be looking for small, temporary decreases in your hearing sensitivity. This will be like the temporary hearing loss, the "cotton in the ears" sensation, we have all commonly experienced after operating loud machinery or going to a loud rock concert. If we detect a certain level of loss of hearing sensitivity (a level that you may not be able to notice) during the tests with ear muffs and/or ear plugs, you will not be allowed to be exposed to any greater strength of BOP while you are wearing ear muffs and/or ear plugs. It is very likely that some, if not most, individuals will have at least one such temporary loss. It is possible that a few individuals will have several such events. If we observe any change in your hearing, even one that we don't consider critical, you will not be exposed again until your hearing has returned to normal.

There is a small risk (less than 1 chance in a hundred of a change in hearing level of more than 10 dB) of permanent hearing loss. The risk of permanent hearing injury resulting from a few incidents of temporary sensitivity loss is not precisely known. However, a panel of NATO scientists and a panel of US hearing specialists have reviewed this question and have concluded that, while such a possibility exists, the risk is small given the design of this study. In order to avoid uncontrolled noise exposures which could

Initials: Volunteer _____ Date _____ Witness _____ Date _____

be hazardous to your hearing and could invalidate the test, you must agree to avoid noisy environments such as shooting guns, hunting, lawn mowing, motorcycle riding, power boating, use of power tools, chain saws, routers, etc., and loud music (rock concerts, discos and loud stereo equipment) for the duration of your participation.

A check for hearing change (and, if necessary, a throat examination) will be done after each exposure and before the next test condition. You will be tested for many possible combinations of strength and number of blasts up to certain limits. The maximum number of blasts that you will be exposed to on any given day is 100. The maximum strength has been determined by the risk of nonauditory bruising as outlined below. After you have completed the tests using one type of ear plugs, you may start additional testing using ear plugs of a different type. Once you have been tested for the pertinent conditions using ear plugs, you may be tested using both plugs and muffs at the same time. You will not be exposed to more than 30 different conditions. The very first exposure condition will not be more than the maximum level allowed by the current policy of The Army Surgeon General (MIL-STD-1474C). Some following conditions will exceed what is now allowed in training.

In addition to conventional audiometry, we will be conducting other tests of your hearing using specialized instruments, e.g.: a swept frequency audiometer to test hearing, a tympanometer to test middle ear, and an otoacoustic emission tester to measure sounds normally coming out of your ears. We will also ask you to complete a synthetic work task to test your mental alertness.

In addition, several questionnaires will be used to determine your opinions about the study and the blast exposures.

Before each exposure, a medical evaluation will be accomplished by the on-site physician assistant/nurse practitioner. This will include a medical self-history form which you wil be asked to complete and a brief physical examination including: weight, temperature, pulse, respiratory rate, blood pressure, otoscopic examination of the ears, nose and throat examination, examination of the chest and heart, and abdominal palpation (pressing on the

abdomen). You will also be given a spirometry test before and after each exposure.

This test involves blowing as hard as possible into a test machine which measures the flow rates.

In addition to affecting your hearing, there is a very small chance that the BOP may cause minor, reversible injury (like bruising) to your larynx (voice box) and trachea (windpipe), your lungs, or your stomach and intestines. There is a great deal of information which indicates that the risk of injury to these organ systems is very small. Even if injury does occur, it will not be serious and will heal quickly with no lasting effects. Injuries occurring to your lungs and windpipe when you have a cold or laryngitis are much more serious than those expected during this study. Other potential sources of risk, although very small, include accidental detonation during explosives handling, flying debris generated by the blasts, noxious gases, heat and cold stresses, and physical examination procedures.

We have set an absolute maximum on the strength of the blast based on the lowest level of blast which will cause minor, temporary injury in a small percentage of exposed large animals. Using hundreds of animals (sheep), we have carefully determined what strength of blast wave, when given 6 to 100 times, causes a barely detectable bruising in the throat in a small percentage of tested animals. This level will be the absolute limit for your exposures.

To examine your throat for evidence of bruising, we must get a look behind and below the base of your tongue. This is done by inserting a small flexible viewing tube into the throat. This procedure may cause you to gag and an anesthetic (numbing medicine) may be necessary. You may experience a nose bleed or retching. This examination will be performed only by a trained physician. Your throat will be examined before any blast exposures and after as many as four of the more intense exposures, at any time the daily review of your medical status indicates, and at the end of your participation. If you do not feel you cannot submit to this procedure, you will not be enrolled in this study.

To qualify for participation in the study, you must be on military

Initials: Volunteer _____ Date _____ Witness _____ Date _____

active duty with less than 5 years of service. You will be disqualified if you have a significant hearing loss or if you show any abnormalities during a physical exam. Final participants will be selected by the recruiting team from all qualified volunteers. If you are selected as a participant, you will receive a medical examination in Albuquerque, NM to determine whether or not you have any medical conditions which might increase your chances of being injured, however slightly. In addition to demonstrating normal hearing, you will have a standard chest x-ray. A breathing test will be done where you will breathe in as much air as you can blow into a machine as forcefully as possible. We will analyze a blood sample (approximately 5 to 7 teaspoonfuls) and a urine sample and we will check your heart with an electrocardiogram. In addition, we will ask you to supply us with a small sample of stool (bowel movement) which we will check for blood. All of these tests are simple and easy to perform and all will be done before you begin the study. The drawing of the blood sample may cause discomfort, bruising, or swelling. If abnormalities are found on the screening tests, you will not be allowed to participate in the study and you will be referred to an appropriate medical facility for evaluation. Information concerning previously undetected, preexisting medical conditions which is developed during your participation in this study could result in your being involuntarily released from active duty. You may not participate in this study if you have a history of allergy to local anesthetics (like Novocaine) or a history of respiratory (breathing) problems, allergic rhinitis (hay fever), sinusitis (inflammation of the nasal passages), or emphysema (a lung disease).

[This next paragraph applies only to female volunteers.] Blast overpressure may have the potential to cause abnormalities in the developing fetus. It is expected that these risks will be insignificant immediately following conception to possibly significant at sometime during the pregnancy. There is a lack of scientific data to be more precise. This impulse noise study will not be open to an individual whose pregnancy test is positive. In order to participate in this study, you should avoid becoming pregnant from the first day of your most recent menses. You should avoid becoming pregnant during the period of the blast exposures. Pregnancy after the termination of the study should present no potential risk to the unborn fetus. You will be given

a pregnancy test approximately every two weeks during the study. To avoid becoming pregnant, you should either abstain from sexual relations or practice a method of birth control. Except for surgical removal of the uterus, birth control methods such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy. The only ways to completely avoid risk to the unborn fetus are (1) do not become pregnant or (2) do not participate in these blast studies.

During the time that you are in Albuquerque, you will be under the supervision of the contract investigators at KAFB. They will arrange for pick-up and drop-off at the airport in Albuquerque, and for your transportation needs while in Albuquerque. You will be expected to maintain an appropriate level of physical fitness during the test. At all times you must remember that we are guests at KAFB in Albuquerque, NM. You are expected to conduct yourselves as soldiers and good citizens. Any misbehavior will result in your being sent immediately to your permanent duty station. Serious misconduct will lead to prosecution under the Uniform Code of Military Justice.

The results of this study will be used in deciding how to protect the hearing of the Army crews who are exposed to mortar or artillery fire. Your participation is entirely voluntary and you are free to revoke this consent and withdraw from the study at any time. If you withdraw, you will travel immediately to your next duty assignment. Your participation in this study is completely voluntary. Your decision to withdraw at any point from the study will involve no penalty or loss of benefits to which you are otherwise entitled and will in no way prejudice your service record.

There will be a physician or a physician's assistant available during all phases of the study should you have any questions regarding your health and participation in this study. You will be participating in this research at no cost to you. In case of a medical emergency at the test site, you will be transported by ambulance to the Kirtland Air Force Base Hospital for follow-up and/or treatment. If you wish to leave the study, notify any of the investigators at KAFB or the medical monitor. We may end your

Initials: Volunteer _____ Date _____ Witness _____ Date _____

participation in the project early if we think it is best for your health and safety.

The point of contact (POC) for explanation of rights as a research subject is: Command Judge Advocate, U.S. Army Medical Research and Materiel Command (USAMRMC), MRMC-AJ, Fort Detrick, Frederick, MD. 21702-5012; DSN: 343-2065 or (301)619-2065.

HANDLING OF DATA

All research data and medical information collected during your participation in this study will be used to achieve the objectives of the study and to help assure your safety and health during your participation. The research data resulting from this study will be presented in military and scientific presentations. It will be available for review and analysis by other scientists. During the conduct of this research we may take photographs, motion pictures, and/or video recordings of you. These may include sound recordings. This visual and acoustic information will be used in public presentations and published in scientific and/or technical reports resulting from the research. These presentations and reports are essential for conveying the scientific and technical aspects of the research to various interested groups. Confidentiality is not guaranteed. Information linked to you by name or other identifiers may be released without your express written permission including photographs, motion pictures, and video tape. Complete confidentiality cannot be promised, particularly to military personnel, because information on your health may be required to be reported to appropriate medical or command authorities. The U.S. Army Medical Research and Materiel Command is eligible to review your research records as a part of their responsibility to protect human subjects in research. During the course of your participation in this research project, you will be provided with any new information that develops that may relate to your willingness to continue to participate. It is the policy of the U. S. Army Medical Research and Materiel Command that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information to be entered into this confidential data base includes your name, address, social security number, study name and dates. The intent of the data base is two-fold: first, to

readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

Before you sign this volunteer agreement, you must answer the attached questions to demonstrate your understanding of the information in this briefing.

You will be given a copy of the volunteer agreement after you have signed it. If you have any questions about your participation in this project, please call collect to one of the following:

Dr. James H. Patterson, Jr.
U.S. Army Aeromedical Research Laboratory
(334) 255-6821

MAJ John Ribera
U.S. Army Aeromedical Research Laboratory
(334) 255-6823

By signing this form I hereby acknowledge I have fully read and understand the contents. Any questions I might have had have been answered to my satisfaction. I am signing this form voluntarily. I further acknowledge I have received a copy of this form to keep.

_____
Signature of Volunteer Date

_____
Typed or Printed Name of Volunteer

_____
Permanent Address

_____
Signature of Witness Date

_____
Typed or Printed Name of Witness

Initials: Volunteer _____ Date _____ Witness _____ Date _____

SIGNATURE OF PERSON OBTAINING CONSENT

I have counseled the above volunteer as to the nature of this research study, the risks involved, and the contents of this consent.

Signature of Person Obtaining Consent Date

Typed or Printed Name of Witness

Initials: Volunteer_____ Date _____Witness_____ Date_____

VOLUNTEER REGISTRY DATA SHEET

THIS FORM IS AFFECTED BY THE PRIVACY ACT OF 1974

1. AUTHORITY: 5 USC 301; 10 USC 1071-1090; 44 USC 3101; EO 9397

2. Principal and Routine Purposes: To document participation in research conducted or sponsored by the U.S. Army Medical Research and Development Command. Personal information will be used for identification and location of participants.

3. Mandatory or Voluntary Disclosure: The furnishing of the SSN is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your participation in the research study.

PART A-INVESTIGATOR INFORMATION

(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

1. Study NR: A-6915 2. Protocol Title: Direct Nonlinear Earplug Study Reverberant Impulse Noise

3. Contractor (Laboratory/Institute Conducting Study): EG&G MSI

4. Study Period: From: 21/6/93 (DA/MO/YR) To: 20/11/98 (DA/MO/YR)

5. Principal/Other Investigator(s) Names(s) 6. Location/Laboratory

(1) JOHNSON, DANIEL L. (Last) (First) (MI) Kirtland AFB, Albuquerque, NM

(2) _____ _____/_____

(3) _____ _____/_____

PART B-VOLUNTEER INFORMATION

(To Be Completed By Volunteer)

PLEASE PRINT, USING INK OR BALLPOINT PEN

7. SSN: ___/___/_____ 8. Name: _____ *(Last) (First) (MI)*

9. Sex: M__F__ 10. Date of Birth: __/__/__ 11. *MOS/Job Series:___ 12. *Rank/Grade:____

13. Permanent Home Address (Home of Record) or Study Location Address:

_____ *(Street)* *(P.O. Box/Apartment No.)*

_____ *(City)* *(Country)* *(State)* *(Zip Code)*

( ) . *(Perm Home Phone No)*

14. *Local Address (If Different From Permanent Address):

_____ *(Street)* *(P.O. Box/Apartment No.)*

_____ *(City)* *(Country)* *(State)* *(Zip Code)*

( ) . *(Local Phone No)*

15. *Military Unit: _____ Zip Code: _____

Organization: _____ Post: _____ Duty Phone No. ( ) .

USAMRDC Form 60-R Revised 1Apr 88 (Supersedes previous editions)

PART C-ADDITIONAL INFORMATION

(To Be Completed By Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

16. Location of Study:

17. Is Study Completed: Y___ N___

Did volunteer finish participation: Y___ N___ If YES, Date finished: ___/___/___ *(DA/MO/YR)*

If NO, Date withdrawn: ___/___/___ *(DA/MO/YR)* Reason withdrawn:

18. Did Any Serious or Unexpected Adverse Incident or Reaction Occur: Y___N___ If YES, Explain:

19.*Volunteer Followup: _____

Purpose: _____

Date: ___/___/___ *(DA/MO/YR)* Was contact made: Y___N___ If No action taken, explain:

20.*Hard Copy Records Retired: Place: _____ File NR: _____

21.*Product Information:

Product: _____

Manufacturer: _____

Lot NR: _____ Expiration Date: _____

NDA NR: _____ IND/IDE NR: _____

*Indicates that item may be left blank if information is unavailable or does not apply. Entries must be made for all other items.

TESTS OF VOLUNTEER UNDERSTANDING OF RISKS

Circle all of the correct answers for each question. There may be one or more than one correct answer for each question. Base your answers on the information discussed in the Volunteer Consent Form that was read during the session:

1. When can you withdraw from this study?

   a. First week
   b. Second week
   c. Third week
   d. Anytime
   e. Never

2. Of the following injuries which are possible in this study?

   a. Bruising of internal organs such as the lungs, stomach, and intestines
   b. Broken bones
   c. Bruising of the voice box and windpipes
   d. None of the above

3. Of the following which are other minor sources of risk?

   a. Heat/cold injury
   b. Cancer
   c. Noxious (harmful) gases
   d. None of the above

4. Is there even a small chance of an injury from an accidental detonation during explosives handling or from flying debris generated by the blasts?

   a. Yes
   b. No

_____ _____

Signature Date

_____

SSAN

Consent for Use of Visual Information Collected During Participation in "Task Order 4: Nonlinear Earplug Study"

I hereby give my permission for the use of visual information collected in conjunction with the study entitled "Task Order 4: Nonlinear Earplug Study," including photographs, motion pictures, and video recordings with sound tracks in which I may be recognizable for public presentations and publication in scientific and/or technical reports.

_____

Signature and Date

_____

Witness and Date

APPENDIX B. BLAST OVERPRESSURE MEASUREMENT PROCEDURES

This is an abbreviated report of:

The Working Group for the Standardization of Muzzle Blast Overpressure Measurements December 4-6, 1979, Ad Hoc Sub Group for Blast Overpressure of the Army Science Board

III. PROPOSED STANDARDIZED TECHNIQUES

The proposed standardization of test procedure for the measuring of the muzzle blast from a weapon is given in this section.

A. Test Layout and Measurements

1. A dedicated test series should be provided for the measurement of blast pressures due to muzzle blast.

2. The transducer locations will be placed radially around the weapon with the muzzle placed at the transducer grid center (0.0) with the tube as nearly horizontal as possible. The 0° - 180° line will coincide with the axis of the barrel of the weapon in a plan (top) view, with the line-of-fire in the 0° direction. Special attention should be given to detail in mapping at the crew location.

3. A minimum of nine rounds will be fired, three each at the minimum useful elevation, the maximum useful elevation, and at an elevation midway between the minimum and the maximum.

4. All mapping transducers will be mounted at a height (to center of sensitive element) of 1.524 m (60 in.) for a standing crew man or 0.80 m (31.5 in.) for a crew man in sitting position.

5. A control transducer shall be located at ground surface on the 135° or 225° radial at a ground distance of 100 calibers measured from a point directly under the muzzle with the tube as nearly horizontal as possible.

6. All mapping transducers will be aligned with the plane of the sensitive element passing through the axis of the barrel of the weapon, thereby measuring at grazing incident to the blast wave. The sensitive element will be up. The intent is to measure the side-on pressure from the primary wave and any secondary explosions (such as those caused by unexpended propellant or detonatable gases outside the muzzle) which occurs along the axis of the barrel. This technique will tend to minimize the arrival of shock waves at transducer incidence angles between 0° and 90° where overshoot and ringing might occur.

7. Test site ambient conditions of atmospheric pressure, temperature, wind velocity, and wind direction at each firing time will be recorded.

8. Measurements shall not be made at wind speeds above 19.3 km/h (12 mph).

9. Best test practices will be used, i.e., transducers should be isolated from ground, shock-mounted, flash/thermal protected, and operated within the specified ambient temperature ranges. Cables should be protected from the blast (in conduit or buried) and run from the transducers away from the direction of propagation of the blast wave. Long lines should not degrade rise time of records.

10. For interior measurements (such as inside self propelled guns or tanks) made where the blast direction is uncertain (or arriving from many directions) the transducer shall be oriented with the sensing surface up, and with the plane of the sensing surface intersecting the center of the major suspected source, i.e., muzzle or open hatch.

B. Transducer Specifications

The transducers to be used for obtaining pressure - time data from the muzzle blast of a weapon shall meet these requirements:

1. The resonant frequency shall be 75 kHz or greater.

2. If the transducer does not have DC response the time constant will be a minimum of 200 ms.

3. The nonlinearity will be 3% or less of the full scale output of the transducer.

4. The transducer shall be chosen to minimize the effects of temperature at the expected temperature range to be used. Output will be corrected from temperature versus sensitivity curves for the individual transducer.

5. The sensitive element shall have a diameter of 6 mm (0.25 in.) or less. Transducer holders or housings should be of a minimum size to mount securely and to incorporate good aerodynamic design so as to minimize interference to the flow over the sensor surface.

6. The acceleration sensitivity will be not greater than 0.014 kPa/g (0.002 psi/g) in the axial direction and not greater than 0.069 kPa/g (0.01 psi/g) in the transverse direction.

C. Transducer Calibration

1. All transducers will be calibrated in a manner consistant with the transducer's time constant, i.e., sinusodual pressure generator, pulse calibrator, dead weight tester, or shock tube.

2. All calibration methods used will be traceable to the National Bureau of Standards.

D. Recording Equipment Specifications

1. Recorders will have a frequency response of DC to 40 kHz or greater as defined by Inter-Range Instrumentation Group (IRIG) standards.

2. FM tape recorder reproduce amplifier output filters will be operated in the linear phase mode.

3. The Data acquisition system will provide a minimum of 25dB signal-to-noise ratio for finally processed data.

E. Data Processing

1. Data will be played back through a low-pass 40 kHz filter of the Bessel type, 36dB/octave rolloff.

2. The digitizing rate shall be a minimum rate of 160,000 samples/sec.

3. All data will be scaled to standard conditions of atmospheric pressure (101.35 kPa) and temperature (288°K) with Sach's scaling laws. The standard values scaled from the measured data (superscript (h)) are found as:

$$\text{peak pressure,} \quad P_s = P_s^{(h)} \left(\frac{101.35}{P_o^{(h)}} \right) \quad ;$$

$$\text{duration,} \quad t = t^{(h)} \left(\frac{P_o^{(h)}}{101.35} \right)^{1/3} \left(\frac{T_o^{(h)}}{288} \right)^{1/2} \quad ;$$

$$\text{and for impulse,} \quad I = I^{(h)} \left(\frac{101.35}{P_o^{(h)}} \right)^{2/3} \left(\frac{T_o^{(h)}}{288} \right)^{1/2} \quad ,$$

where the subscript (o) is used for ambient conditions.

4. Analog to digital converter shall have a 10 bit word size or greater.

F. Data Report

1. The data report will present only pressure-time data scaled to standard conditions.

2. SI units will be used with dB's or psi added where needed.

3. Representative pressure-time traces will be included in the report with an exact description of how peak pressure values were obtained from the data.

4. A block diagram of recording-data system will be given including manufacturer, type, and model number of each component of the system.

5. A detailed description including serial number, model number, etc., of all components of the weapon system test along with type and lot number of projectiles and charges will be included. This description will be sufficiently detailed as to allow a complete reconstruction of the weapon system tested.

IV. EVALUATION OF DATA AND TECHNIQUES

During the course of the working group meeting on 4 - 6 December 1979, the existing data regarding M198 muzzle blast overpressures was reviewed in detail. The conclusion of the working group concerning the comparison of data acquired by different organizations was that any comparison of existing data sets was improper because the various data sets were obtaine under different circumstances. The M198 data measured by the Materiel Testing Directorate (MTD) at Aberdeen Proving Ground was taken at a height of 60" above the ground surface and with a very sparse mapping pattern. The data measured by the U.S. Army Aeromedical Research Laboratory (USAARL) at Yuma Proving Ground was taken at a height of 46" above the ground and employed a much more detailed mapping pattern particularily in the crew location area. The variation in height above the ground plane could have a significant effect on the strength of ground plane reflections. Additionally the probability of very complex wave form patterns in the crew area, due to wave interactions with the various M198 components in and surrounding that area, along with the different mapping patterns, could very well account for the higher values obtained by USAARL at specific locations within the crew area. Also during the review and discussion of the data sets it was revealed that there exists a serious doubt as to the similarity of the muzzle brakes used during the two test series. There is apparently a serious question in the minds of the USAARL personnel as to whether the muzzle brake used on the M198 during the Yuma tests was of the same type and design as that currently employed. The working group concluded that the data sets are sufficiently different and therefore that comparisons should not be attempted.

The working group was advised by Dr. Patterson, USAARL, that there does exist within USAARL another set of blast overpressure data for the M198 taken at Aberdeen Proving Ground in November - December 1978 that is not yet reported. A review of the procedures and techniques used in the recording of this data indicates that it is in compliance with the proposed standardized techniques contained in this report with the exception of the availability of data on ambient temperature, pressure, and wind conditions at the time of the testing. Since however, it is the recommendation of this working group that all data be scaled to accepted standard conditions (barometric pressure of 14.7 psi and ambient temperature of 15° C) it is the conclusion of this group that the variation of actual conditions and standard conditions would have been minimized and as a result the scaling factors would not be significantly different from one (1).

Assuming that the recommendations of this working group are accepted, it would then seem reasonable to conclude that the currently unpublished data from USAARL would be an accurate and reliable data set and therefore represent the blast overpressure field around the M198. If these recommendations and conclusions are accepted there would appear to be no justification or requirement for additional testing of the M198.

V. RECOMMENDATIONS

1. If the proposed standardized techniques for muzzle blast measurement are accepted, it is recommended that they be incorporated into MIL-STD-1474B(MI), 18 June 1979.

2. It is recommended that the currently unpublished data set from the USAARL test firings of the M198 should be accepted as the reliable blast pressure field existing around the weapon when fired.

APPENDIX C. DETERMINING ALLOWABLE INTENSITY SEQUENCE FOR A GIVEN DISTANCE AND DETERMINING THE SEQUENCE OF EXPOSURES FOR AN INDIVIDUAL

Exposure Sequences for a Group

The study design calls for a subject to sit some distance (D) away from an explosion. The amount of explosive or the number of exposures is increased each time the subject has no ill effects from the prior exposure. A starting point and some rules for incrementing exposures must be chosen to meet three objectives. First, we must start at a point that is highly unlikely to cause any harm even to a relatively sensitive individual. We accomplish this by beginning below the Z curve of MIL-STD-1474B. Secondly, we must increment in steps small enough to insure that an individual subject will not be significantly injured in going rom a safe level to the more intense subsequent level. Thirdly, the incremental steps in a level must not be so small as to make the study of interminable length. The latter two points are addressed by setting the rule that the total energy of an exposure condition, E*(D,A,N), will be no more than doubled in going to the next exposure level. This is done initially by keeping the number of exposures constant and increasing the explosive charge. Once some limit to intensity is reached, the exposure energy is increased by doubling the number of exposures. Although the actual conditions of the starting point and the subsequent doubled energy points will have to be measured, we can estimate what these values might be.

Table 1 shows an example of the calculated starting and doubled energy steps for distances of 8, 5, 3, and 1.5 m. Once thee are determined, they are plotted as isodistance curves on axes of peak pressure versus impulse, Figure C-1.

Figure C-2 displays doubled energy exposure conditions for two

hypothetical distances, D_1 and D_2. Figure C-3 illustrates how these sequential energy steps can be translated into an exposure matrix. Figure C-3 shows how the points for D_2 from Figure C-2 are translated into an exposure matrix. The exposure matrix limits may be changed during the course of the study if a sufficient number of auditory failures occur. For this study, 11 failures would close out a matrix condition. The crosshatched cells of the exposure matrix indicate exposure conditions which are not allowed. Note that the nonauditory limiting curve for N $\leq$100 disallows any exposure above the A= 4 level if N .25. The manner in which an individual will proceed through the exposure matrix is explained in Appendix D.

Exposure Sequence for an Individual

A subject will be exposed to variable intensities (A) and number (N) of blasts at a given distance (D). The distance will be fixed and a subject will be exposed at only one distance. The subject starts using First Level Hearing Protection (FLHP) at an exposure condition which is determined as being safe by MIL-STD-1474B for six exposures.

For the first subjects tested at distance D, the exosure matrix will apear similar to Figure C-3. Each cell represents a possible exposure condition, E(D,A,N,H), for all levels of hearing protection. Initially, limits on intensity level and number are set by the study design and the interaction of the non-auditory limits and the characteristic increase of exposure energy for increasing charge weight at a given D (Figure C-3). The exposure

matrix might change from that in Figure C-3). The exposure matrix might change from that in Figure C-3 to that in Figure C-4 where three additional cells (indicated by a single diagonal) are blocked from future exposures because of cumulative failures. In any case, each individual should begin his exposure with a well-defined matrix indicating allowable exposure condtions for FLHP and SLHP. After each exposure the subject will be given a series of audiograms. The subject moves from one test condition to the next in accordance with the rules below. The purpose of exposure rules is to logically explore the limits of our ability to adequately protect hearing (TTS, 25 dB) on axes of exposure intensity and numer of exposures while safeguarding the individual subject.

The following are the basic rules governing sequential exposures:

1. The first exposure for all subjects will be the lowest intensity for the distance and the lowest number of blasts with FLHP.
2. A pass at any exposure condition will usually result in the next exposure being at a doubling of total energy. Intensity will be increased first. If intensity cannot be increased, then number will be increased. It should be noted that the new total energy will be less than double the previous value only in those cases where the number of blasts is increased from 25 to 50 such that the W must be decreased to conform to the accompanying changes in the nonauditory limit.
3. Following a failure, the next exposure will usually be at

a halving of the total energy at which the failure occurred. This will be achieved by reducing intensity alone, unless a pass at that condition has already occurred. In the latter case, a combination of increased number and decreased intensity will be used to avoid retracing of the path. It should be noted that the new total energy will be less than half the previous value only in those cases where the number of blasts is increased from 25 to 50 such that the W must be decreased to conform to the accompanying change in the nonauditory limit.

4. If an exposure at intensity A results in a conditional failure at intensity A+1, the next expsoure will usually be at a total energy equal to the condition resulting in the conditional failure. The intensity will be reduced to A-1 and the number doubled. It should be noted that the new total energy will be less than the previous value only in those cases where the number of blasts is increased from 25 to 50 such that the W must be decreased to conform to the accompanying change in the non-auditory limit.

5. A conditional failure at intensity A+1 (see Rule No. 4) will be administratively removed as a result of a pass at intensity A with a larger number of blasts.

6. A failure at an intensity for some number of impulses, N, will preclude future exposures to that intensity for all numbers greater than N for the same level of hearing

protection.

7. A subject has completed the matrix of exposures when he passes at the maximum number and maximum permitted intensity or when he scores a pass and a fail at the maximum number.

8. After a subject completes the matrix with FLHP, he will start exposures with SLHP at the lowest N among:

   a. The first exposure condition which the subject by passed with FLHP because of administrative closure.

   b. The condition for which the first failure or conditional failure with FLHP was registered.

9. After a subject completes the matrix with SLHP, he will start exposures with TLHP at the lowest N among:

   a. The first exposure condition which the subject by passed with SLHP because of administrative closure.

   b. The condition for which the first failure or conditional failure with SLHP was registered.

10. If a subject using SLHP would enter an exposure condition as a result fo the above rules in which he had already passed with FLHP, then that condition will be an automatic pass.

11. After 11 failures at a given level of hearing protection have been accumulated at intensity A for number N, that condition will be administratively closed to exposure of any future subjects.

12. Any subject who does not recover within 24 hr from an exposure will be precluded from any additional exposures.

APPENDIX D. DETERMINING CRITICAL THRESHOLD SHIFT

A change in hearing sensitivity, as measured by an audiogram, which recovers in a short period of time is termed a temporary threshold shift (TTS). There is general agreement that a 25-35 dB TTS may be experienced on occasion without any significant risk of a permanent hearing loss (NATO, RSG.6, 1987; Mills, 1984; Kryter and Garinther, 1966; Ward et al, 1961). Epidemiologic data from studies with continuous noise also suggest that a TTS induced on a regular (daily) basis for a long period (years) is unlikely to result in a permanent threshold shift (PTS) that is larger than the TTS. It is the objective of this study to determine the exposure conditions which produce a 25 dB TTS in a specified percentage of a study population exposed to impulse noise.

In order to find, with some degree of confidence, the exposure conditions which will induce a 25 dB TTS in a proportion of the population, it is necessary to induce a somewhat higher TTS in individual participants. Obviously, the size of this TTS must be minimized in order to protect the individual. We know that once a TTS begins to build, that exposure to a more energetic noise environment will only result in a greater TTS with some undefined risk of permanent loss. The rules which are developed in this Appendix are intended to minimize the risk to the individual while permitting the study goal of determining the population characteristics as accurately as possible. In establishing pass-fail criteria for use in this study, we recognized that after each exposure we must make a decision based on the data whether to

proceed to the next more severe exposure. There are two fundamental problems in making such a decision. First is the inherent variability in the audiometry which will produce an error variance in the observed TTS's. TTS's may be over or under estimated due to this variability. Thus, both of the types of errors from classical statistical decision theory are possible. If our estimates of TTS are too high, we will falsely declare a failure. If this happens often, the results of the study will be biased. If our estimates of TTS are too low, we will falsely pass an individual who will then receive a more energetic exposure and perhaps suffer a larger than desirable TTS with increased risk of PTS.

In addition to the statistical uncertainty inherent in measuring an audiogram, there is a second issue which must be addressed in building the pass fail criteria. As exposure severity increases, the true TTS (tTTS) can grow rapidly. That is, a small tTTS at one exposure condition may be followed by a TTS twice as large at the next exposure condition (Ward et al, 1961). In practical terms, if we observed a tTTS of 20 dB, we might expect a tTTS as large as 40 dB to result from a doubled energy exposure. While 20 dB is below our target value of 25 dB, and we do not wish to declare a failure for the exposure which produced it, we do not wish to expose the individual to the next intensity which might lead to a 40 dB TTS. This dilemma leads us to the concept of a conditional failure. Under this concept, a pass will be entered

for the current exposure, however, a conditional failure is entered for the next higher intensity without exposing the individual to that higher intensity. Thus, we will in fact have two criteria: one for a conditional failure and a different criterion for an immediate failure.

In constructing pass-fail criteria, we must first select the variables on which to base the decision. Since we are testing a number of frequencies, there is uncertainty which frequency will show the largest TTS. Regardless of which frequency shows the largest shift, our goal is to declare an immediate failure when the TTS at any frequency exceeds 25 dB. We also desire to declare a conditional failure when there is high likelihood that the TTS would exceed 25 dB at the next more energetic exposure. To achieve these goals, several decision variables and formulas for criteria were considered. Even though the basic audiometric data can be presumed to be normally distributed, the statistical properties of these decision variables are not known. Therefore, Monte Carlo simulation of the audiometric data was used to evaluate the performance of these variables. The result of these analyses was that the highest observed TTS, which we call L, is the basic variable on which to base the pass-fail decision.

In developing the pass-fail criteria, the governing philosophy was to balance the likelihood of the two types of errors (false passes and false failures). It is not possible to achieve this in a general sense due to the large number of patterns of TTS across

the test frequencies. However, several archetypical patterns o tTTS were adopted for developing the failure criteria. Th archetypical TTS pattern was a true TTS of zero at all except on frequency. Within the Monte Carlo simulation it does not matte which frequency shows the non-zero TTS. A second pattern, had tw non-zero frequencies. The third consisted of a pattern in whic 4.0 kHz shows the largest TTS and 0.5 kHz and below show no TT while frequencies between 0.5 and 4 kHz and frequencies between and 8 kHz show a TTS that gets progressively smaller as th frequency moves away from 4 kHZ. This pattern is similar to TT observed in human experiments (Ward et al, 1961).

These architypical TTS patterns were used to estimate th median value of our measure, L, when the true highest TTS was 2 dB. Thus when the tTTS was just under 25 dB the probability of false failure would be approximately 0.5. Conversely, when th tTTS was just above 25 dB, the probability of false pass would b approximately 0.5. As the tTTS moves away from 25 dB the prob abilities of each type of error drop at a rate which depends o the variability of the audiometry.

During the Monte Carlo simulations the effect of the size o the audiometric variability on the median value of L was explored Very little effect was noted over the range of expected standar deviations, 2-5 dB for our first archetypical tTTS pattern. Th second and third TTS patterns did show a dependence on th audiometric variability over this range. Therefore, the failur

criteria will have to be tailored to each subject based on his audiometric variability as estimated from baseline data.

The median value for L using our first archetypical tTTS pattern was 25 dB, ie., our failure target value. However, as the audiometric variability increased, the median of L increased above 25 dB for the other two patterns. If we selected 25 dB as our failure criterion, it would perform well when the tTTS conformed to the first pattern, but would produce too many false failures when two frequencies shifted or when many frequencies shifted. To overcome this problem, a decision rule was developed to attempt to categorize the data by the tTTS pattern from which it was likely to have come. This procedure is shown schematically in Figure 10. If the observed TTS pattern has one frequency 10 dB greater than all the others, the failure criterion, is 25 dB. If the highest and second highest observed TTS's are within 5 dB and the third highest is 10 dB below the second, then a criterion, C2, derived from the second archetypical pattern is used. Otherwise, a criterion, C3, based on the third archetypical pattern is used. The equations for these criteria are:

$$C1 = 25$$

$$C2 = 25 + SD \qquad \text{for all SD}$$

$$C3 = 25 + SD - 2.7 \qquad \text{for all } SD \geq 3.0$$

$$= 25 \qquad SD < 3.0$$

We now return to an issue raised earlier. A tTTS just under 25 dB should not be counted as a failure for the current exposure condition. However, it is large enough that if we expose the individual to the next more energetic condition the TTS would likely become unacceptably large with increased risk of permanent injury. It should also be noted that false passes with tTTS greater than 25 dB present this same problem. In order to reduce the likelihood of such an occurrence, we introduced the concept of a "conditional failure." This concept allows us to register a pass for the current exposure condition and a "failure" for the next more energetic condition without exposing the individual to the higher energy.

To implement this concept, we adopt a second set of criteria developed in a manner analogous to the failure criteria described above except that the tTTS target level for the conditional failure is set to 15 dB.

These criteria for the three archetypical tTTS patterns are:

$$C4 = 15$$

$$C5 = 15 + SD \qquad \text{for all } SD$$

$$C6 = 15 + SD - 2.0 \qquad \text{for all } SD \geq 2.0$$

$$= 15 \qquad SD < 2.0$$

In order to test these criteria against tTTS patterns other than the ones for which they were developed, another Monte Carlo

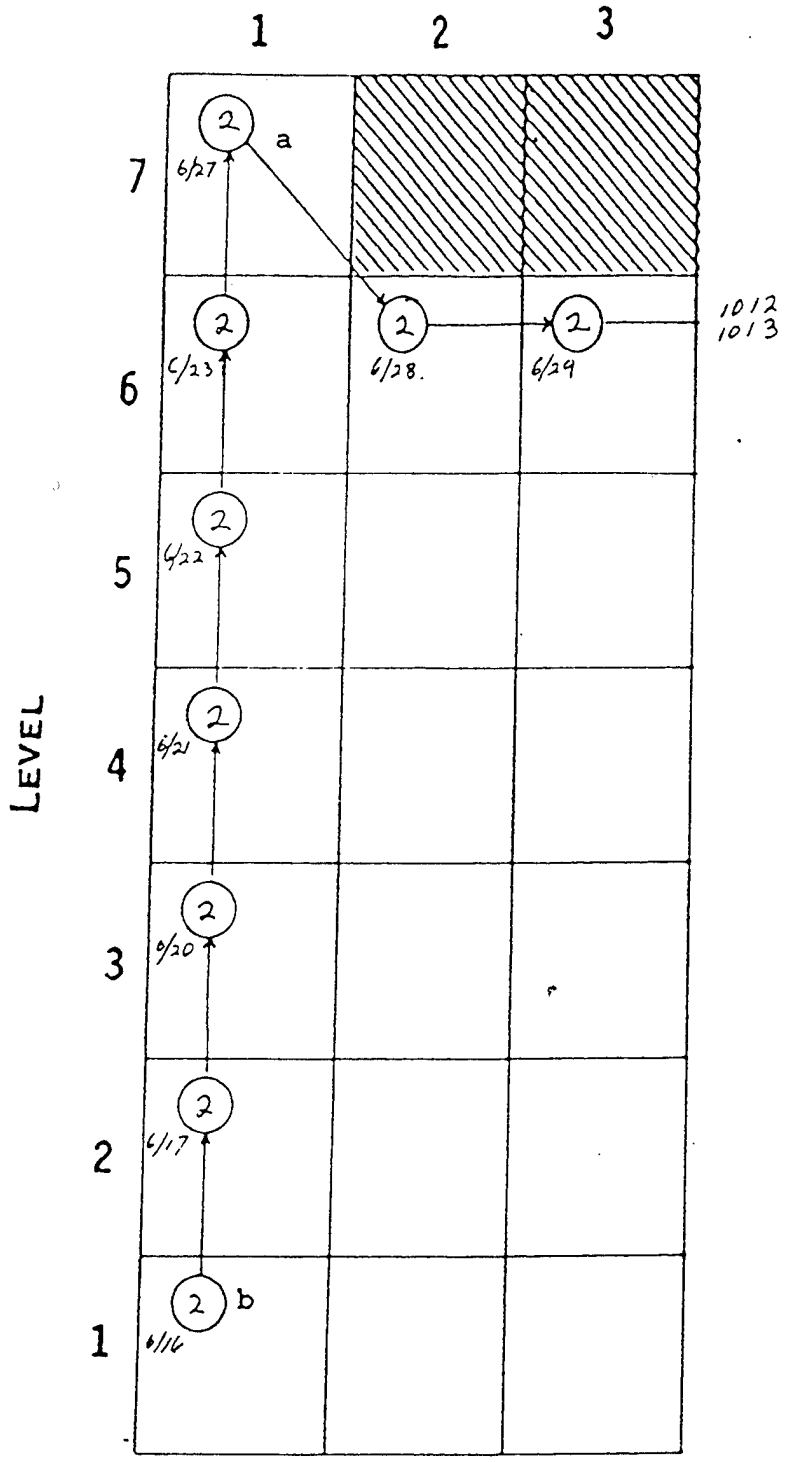
simulation was undertaken. This time random patterns of tTTS were generated subject to the constraint that the maximum tTTS in a pattern was uniformly distributed over the interval from 0 to 40 dB. All other tTTS were uniformly distributed over the interval from 0 to maximum tTTS. Using these patterns, estimates of the probabilities of the two types of errors (false pass and false failure) were estimated when the maximum tTTS was 15, 20, and 25 dB. These probabilities are summarized in Table 4. First, as we might expect, both types of error rates increase generally with SD. For a SD of 5.0, the probability of a false pass given a tTTS of 20 dB exceeds 0.1. This is unacceptably high and led us to restrict the pooled standard deviation in the master baseline to 4.0 dB. Second, the two types of error rates are about the same for a tTTS of 20 dB. This type of symmetry is an expected result of the fact that 20 dB is half way between our target failure values of 15 and 25 dB. By the time the tTTS reaches 25 dB, the probability of a false pass is very low for SD values of 4.0 or less, which is critical for the protection of the volunteers.

In simple terms, the figures in Table 4 suggest that as many as 1-2 of the 60 subjects planned for the study might pass an exposure when their tTTS is marginal (20 dB). They could then be exposed to a double-energy condition which might produce a tTTS on the order of 40 dB. On balance, the pass-failure criteria appear to protect the subjects adequately without excessively biasing the results of the study. The results of over 240 subjects of the previous study have borne out this procedure.

Table I-1. Probability estimates of the two types of errors for selected values of tTTS.

SD	FALSE PASS FOR tTTS			FALSE FAIL FOR tTTS		
	15 dB	20 dB	25 dB	15 dB	20 dB	25 dB
1	0.620	0.000	0.000	0.000	0.000	0.346
2	0.463	0.002	0.000	0.000	0.007	0.467
3	0.530	0.035	0.000	0.000	0.034	0.503
4	0.558	0.088	0.005	0.005	0.071	0.453
5	0.543	0.158	0.019	0.017	0.117	0.439
6	0.545	0.202	0.034	0.044	0.177	0.436
7	0.533	0.217	0.055	0.074	0.199	0.458

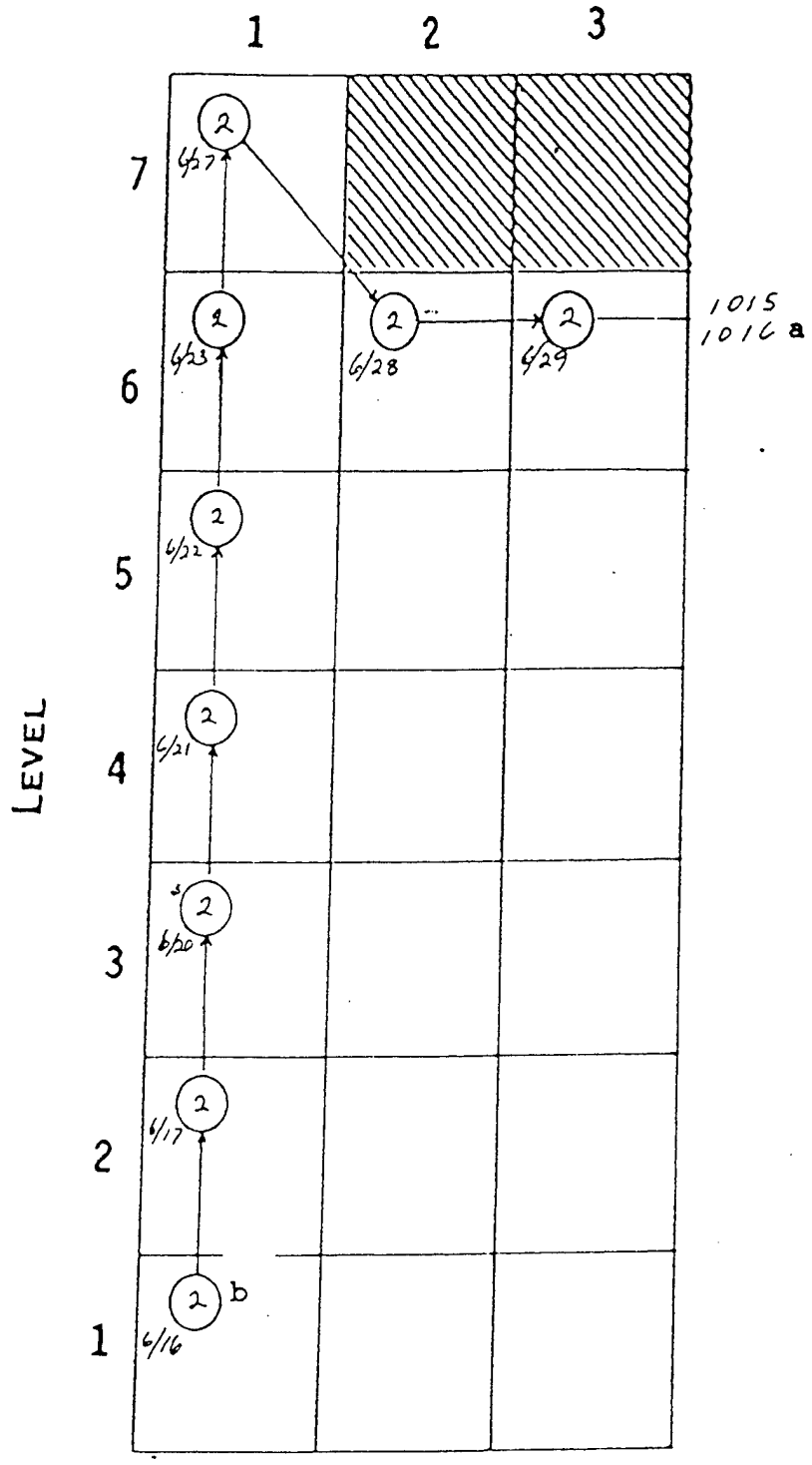
APPENDIX E. SUMMARY OF EACH SUBJECT'S PATH THROUGH THE MATRIX



Appendix E-1. Exposure Matrix for Subjects 1012 and 1013, June 1994.

a. Subject 1012 had positive guaiacs after Level 6 on the weekend of 25-26 June 94; negative thereafter.

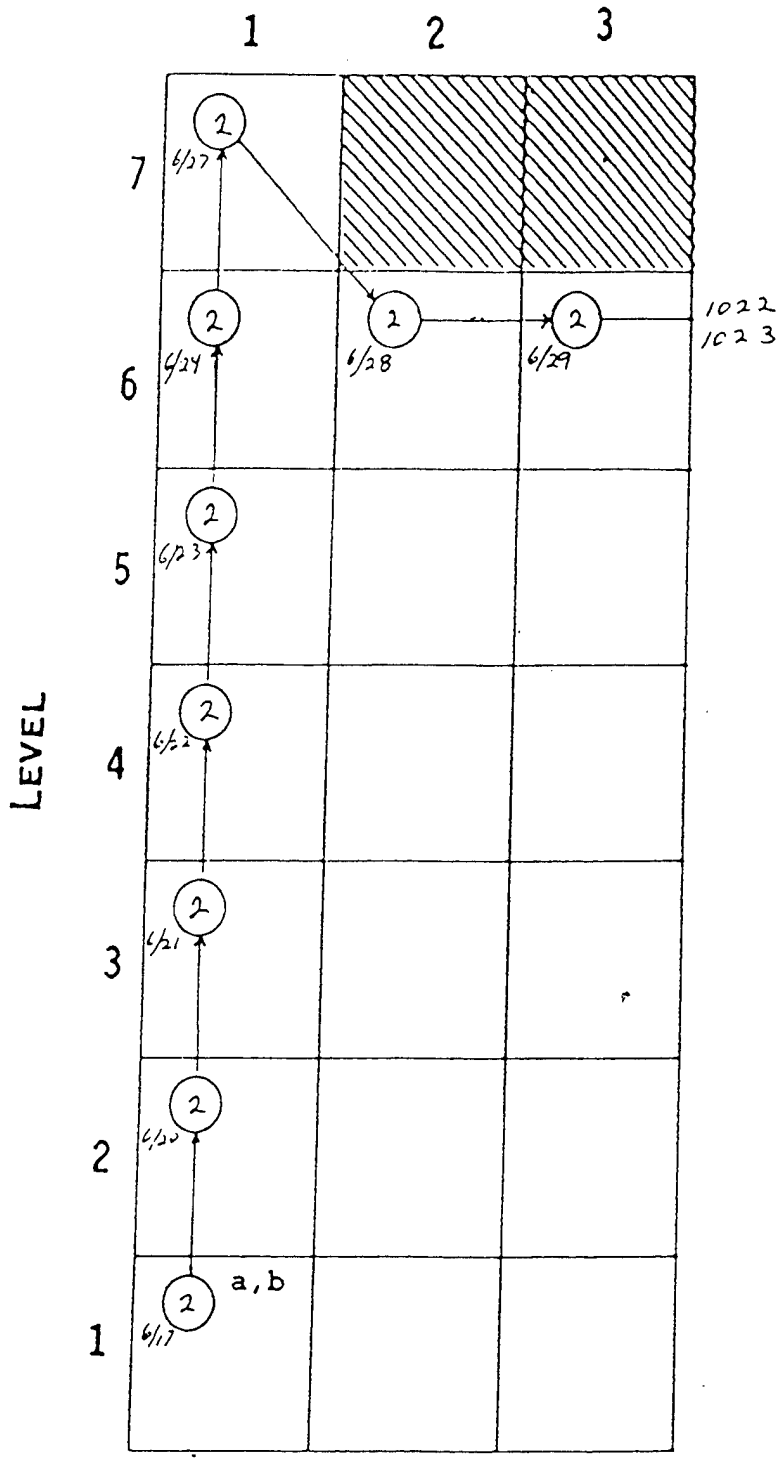
b. Levels "00" and "0" were passed on 14 and 15 June, respectively.



Appendix E-2. Exposure Matrix for Subjects 1015 and 1016, June 1994.

a. Subject 1016 had a positive guaiac on 1 July 94; negative thereafter.

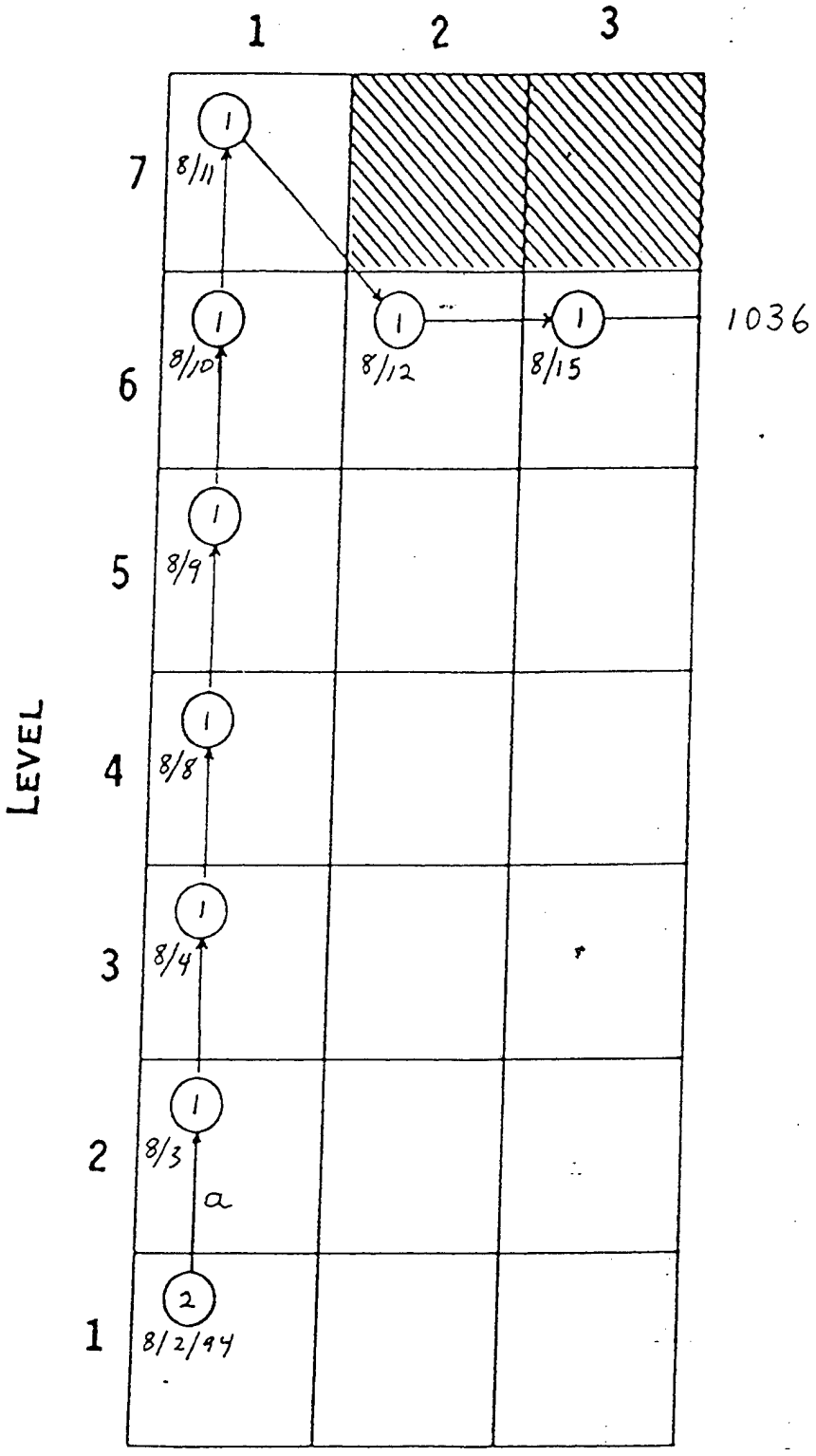
b. Levels "00" and "0" were passed on 14 and 15 June, respectively.



Appendix E-3. Exposure Matrix for Subjects 1022 and 1023, June 1994.

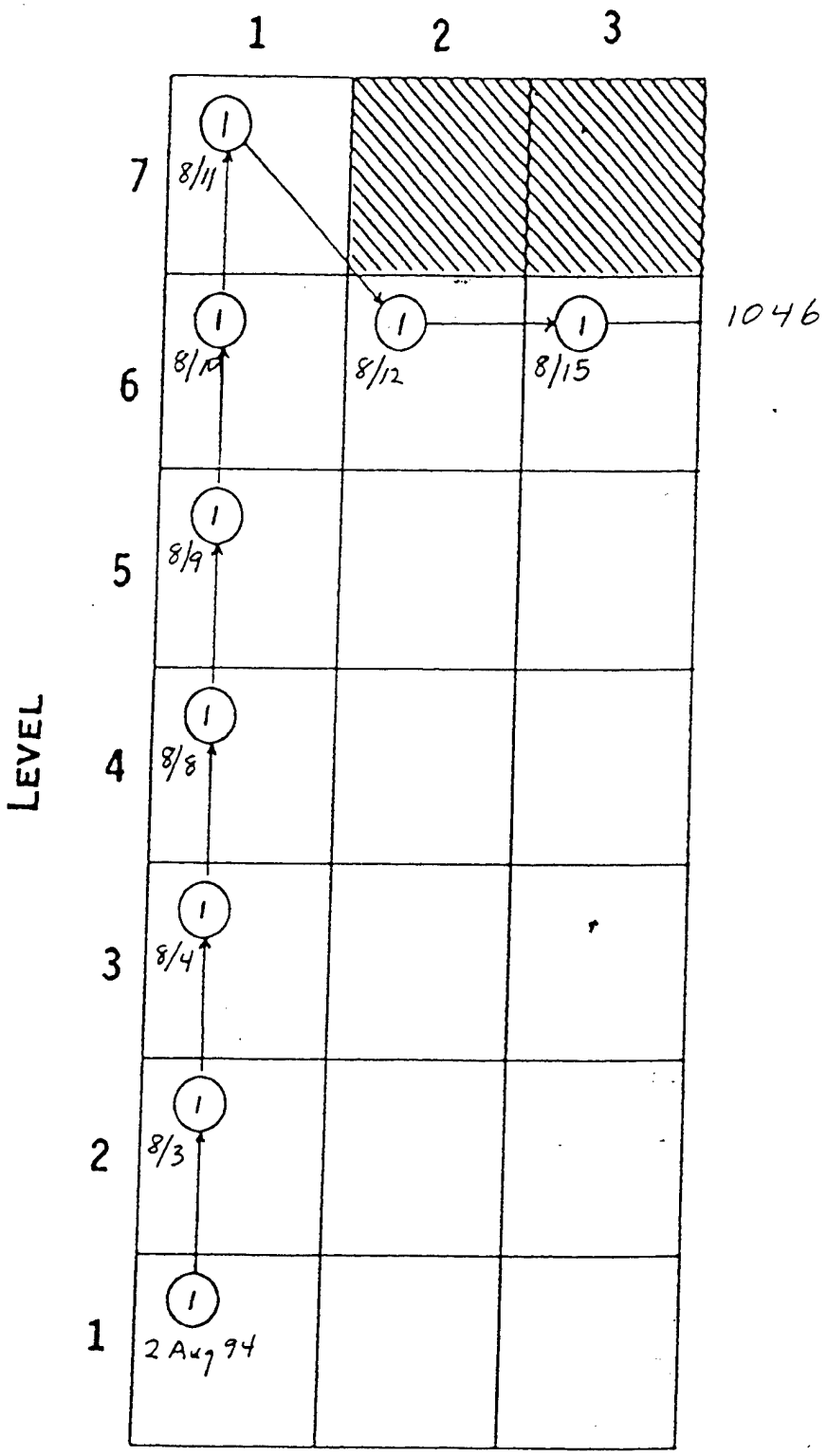
a. Subject 1022 had a positive guaiac after Leve 1; negative thereafter.

b. Levels "00" and "0" were passed on 15 and 16 June, respectively.

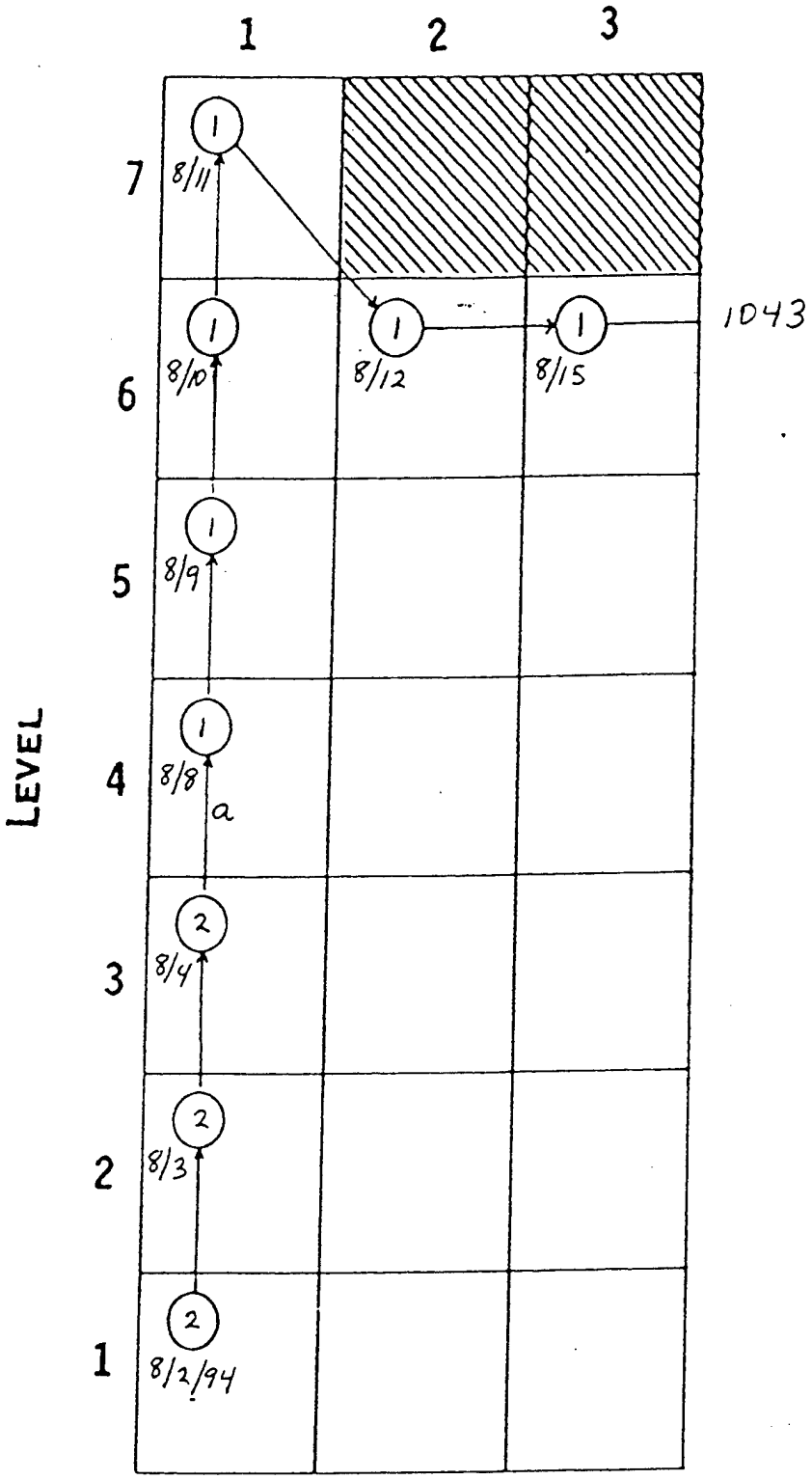


Appendix E-4. Exposure Matrix for Subjects 1035 and 1036, August 1994.

a. Subject 1035 elected to stop after Level 1.

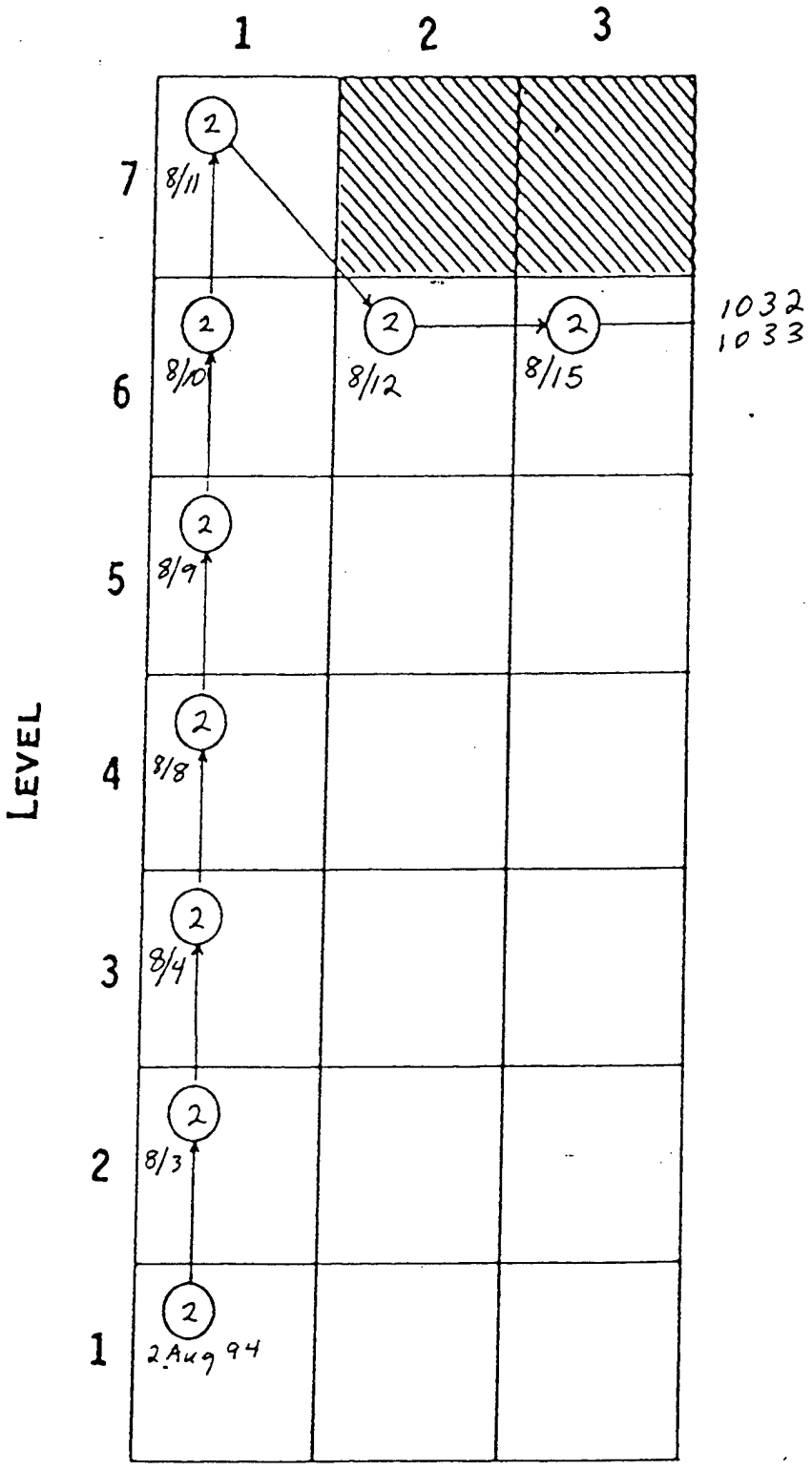


Appendix E-5. Exposure Matrix for Subject 1046, August 1994.

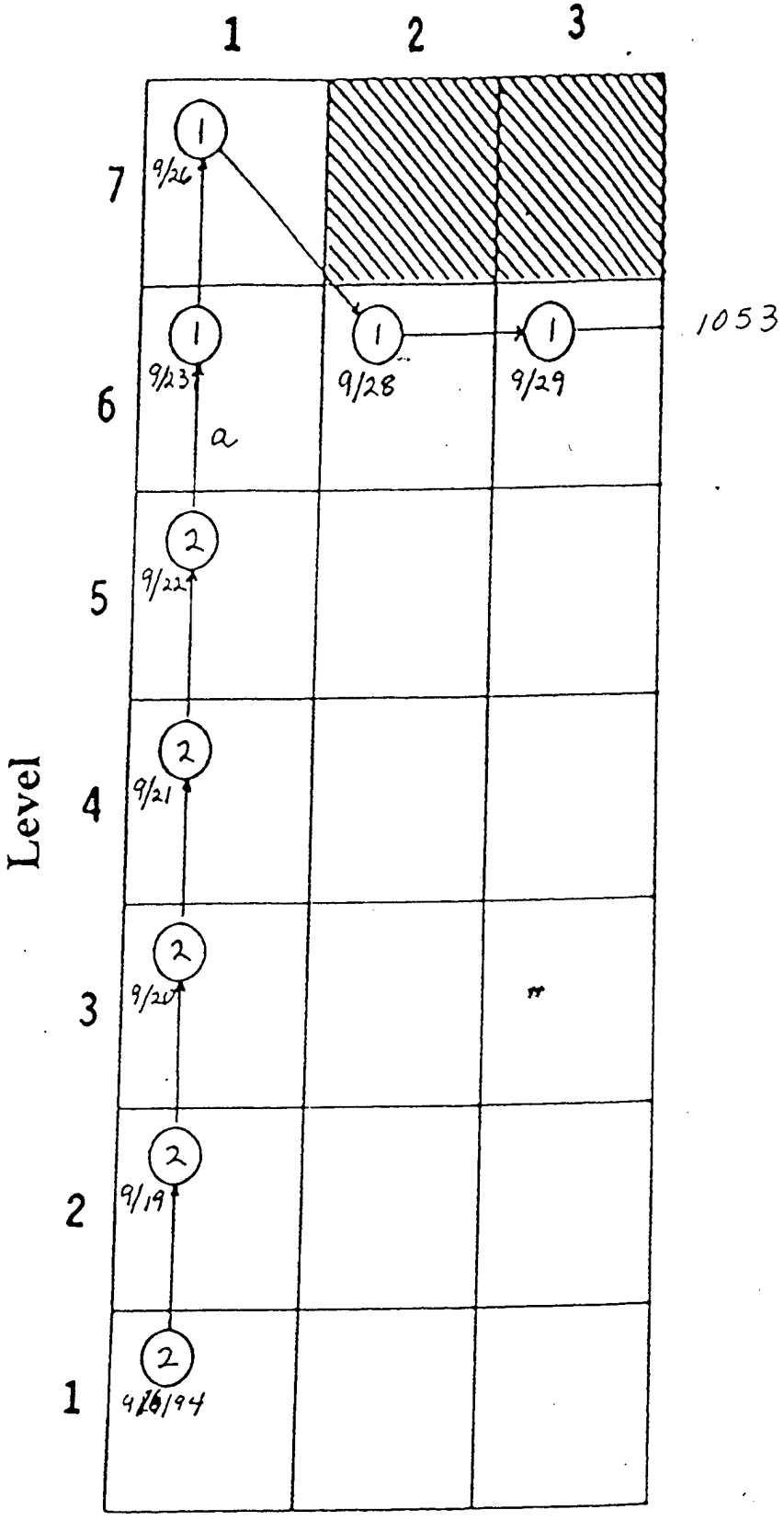


Appendix E-6. Exposure Matrix for Subjects 1042 and 1043, August 1994.

a. Subject 1042 elected to stop after Level 3 because of family problems.

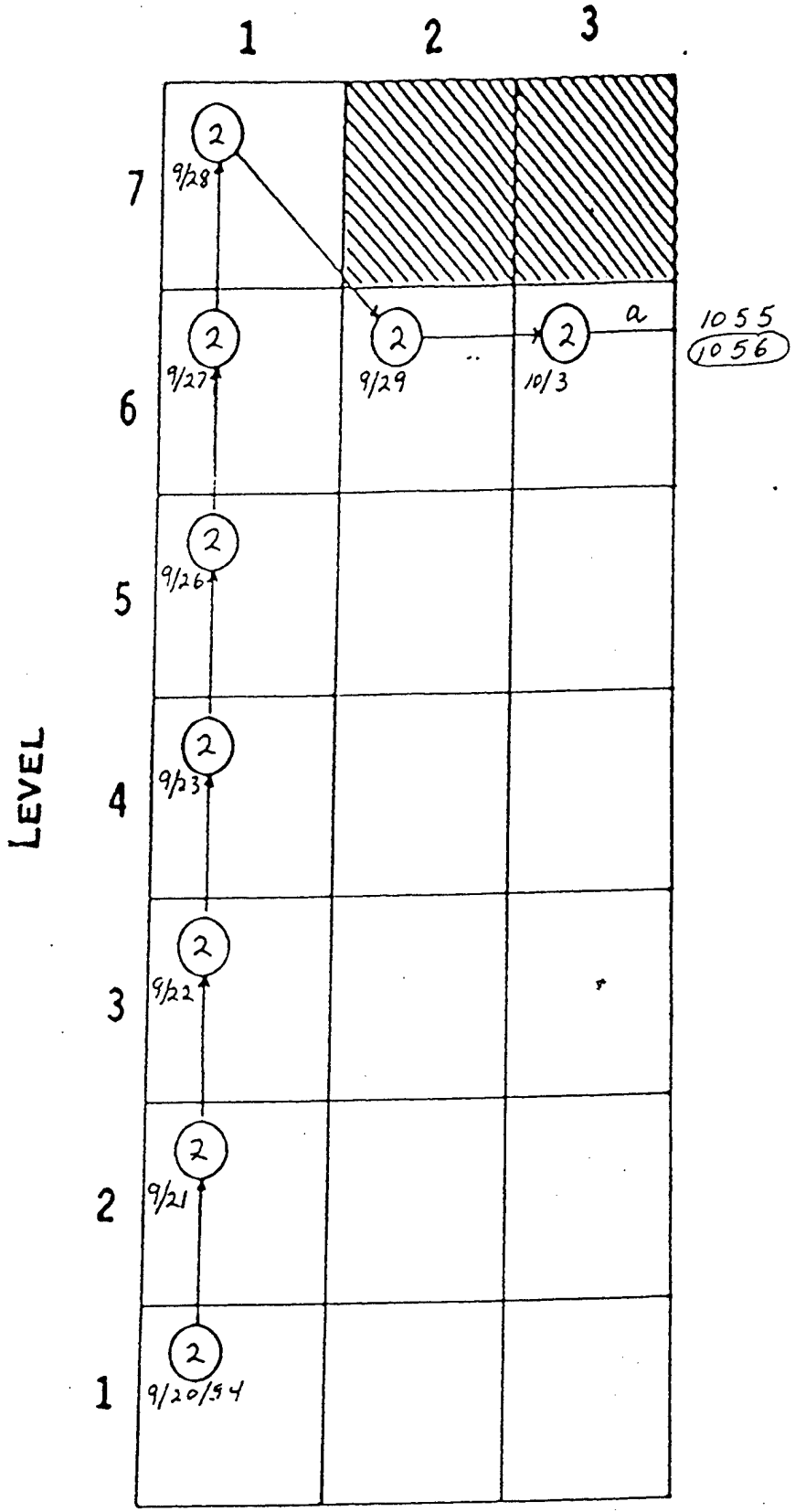


Appendix E-7. Exposure Matrix for Subjects 1032 and 1033, August 1994.



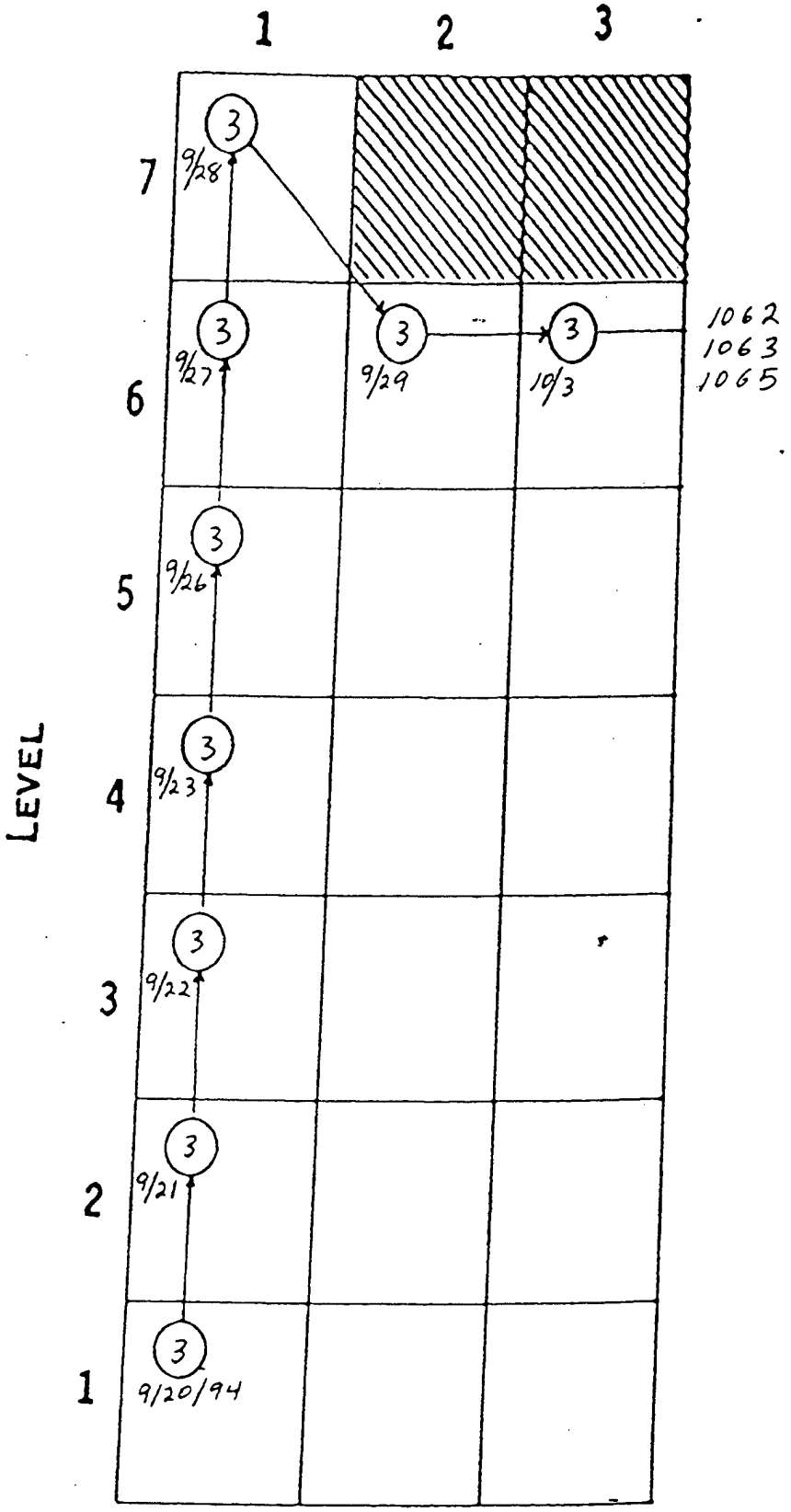
Appendix E-8. Exposure Matrix for Subjects 1052 and 1053, September 1994.

a. Subject 1052 was not exposed further because chronic ulcers.

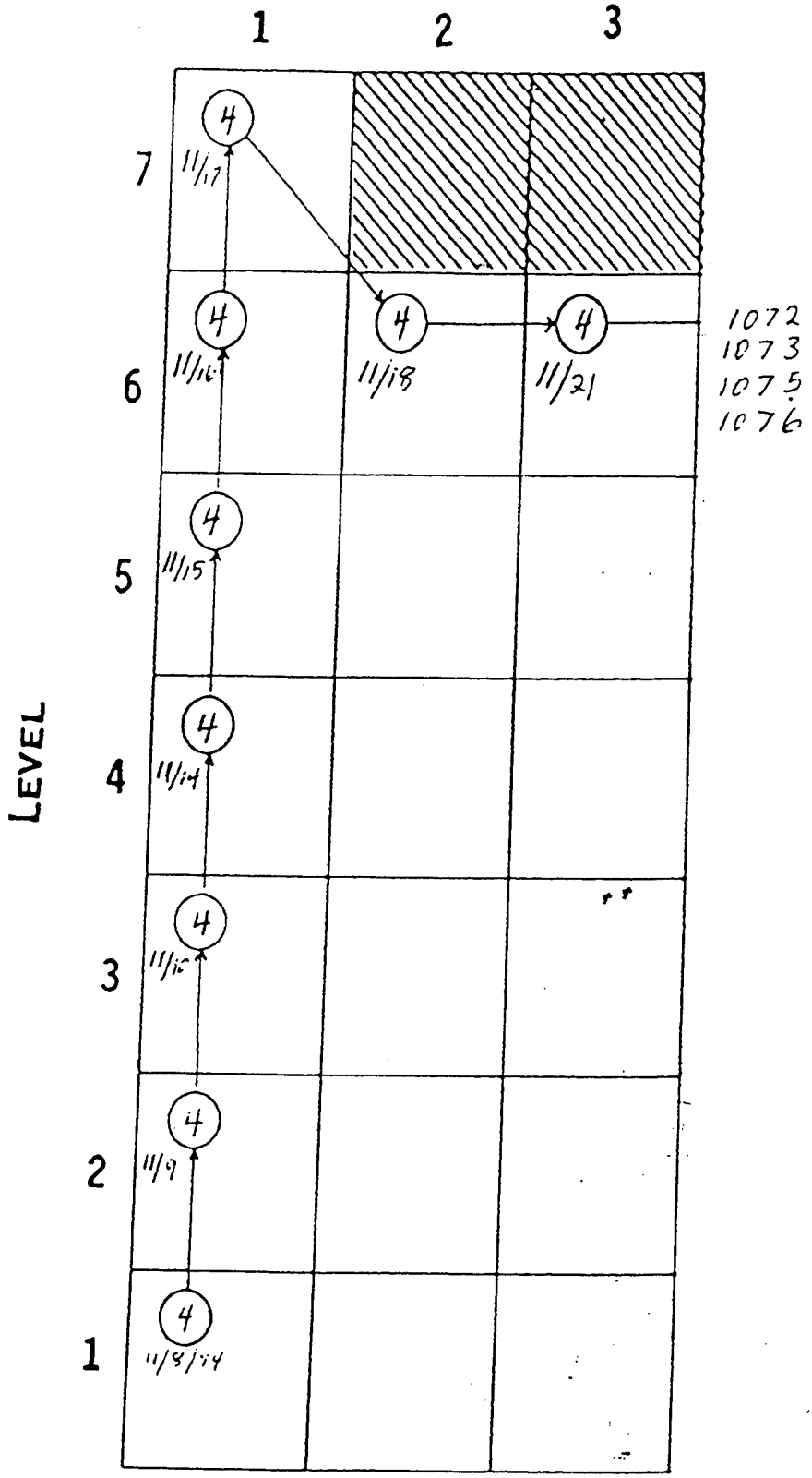


Appendix E-9. Exposure Matrix for Subjects 1055 and 1056, September 1994.

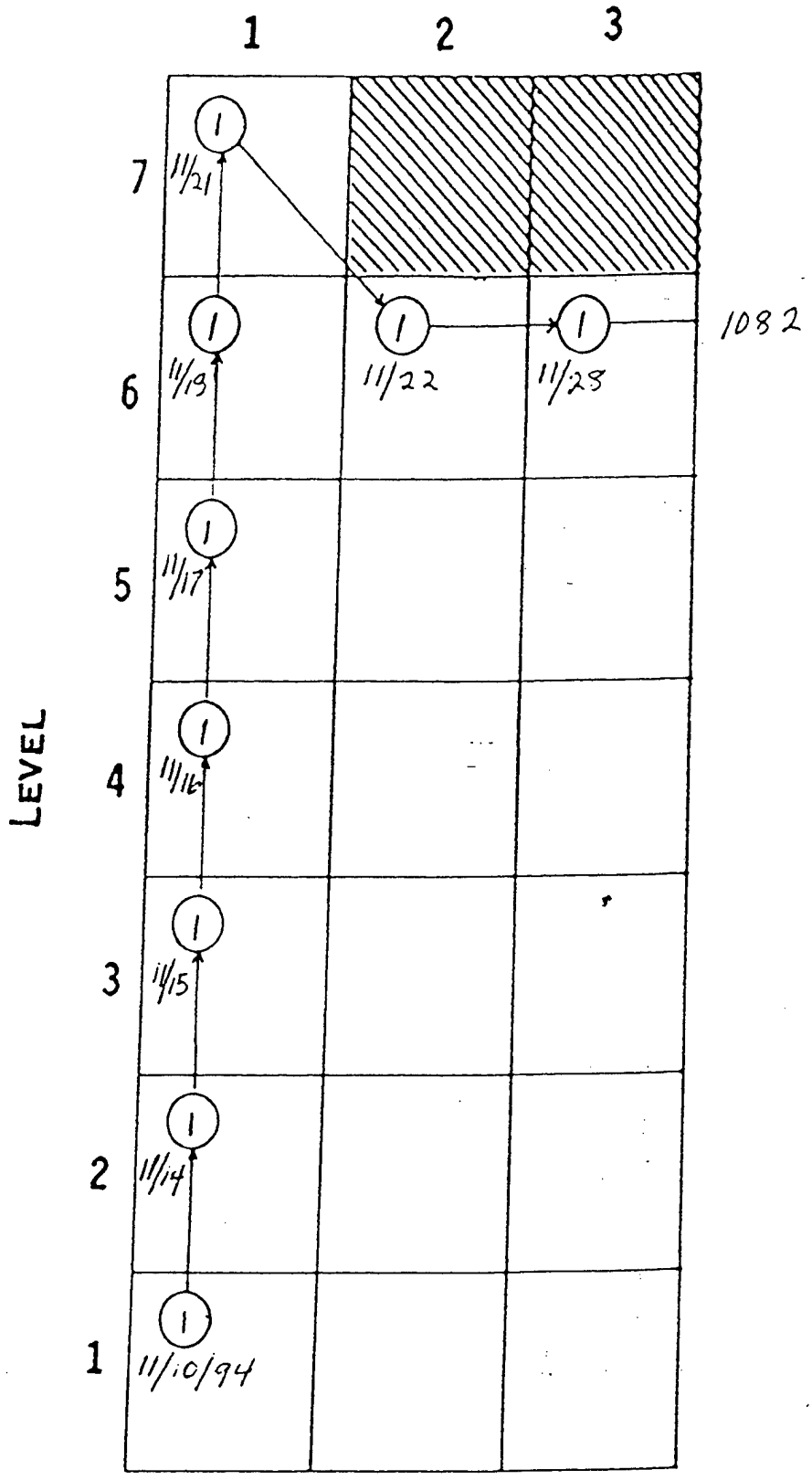
a. Subject 1056 was a conditional failure after condition 6/3 and was not exposed further.



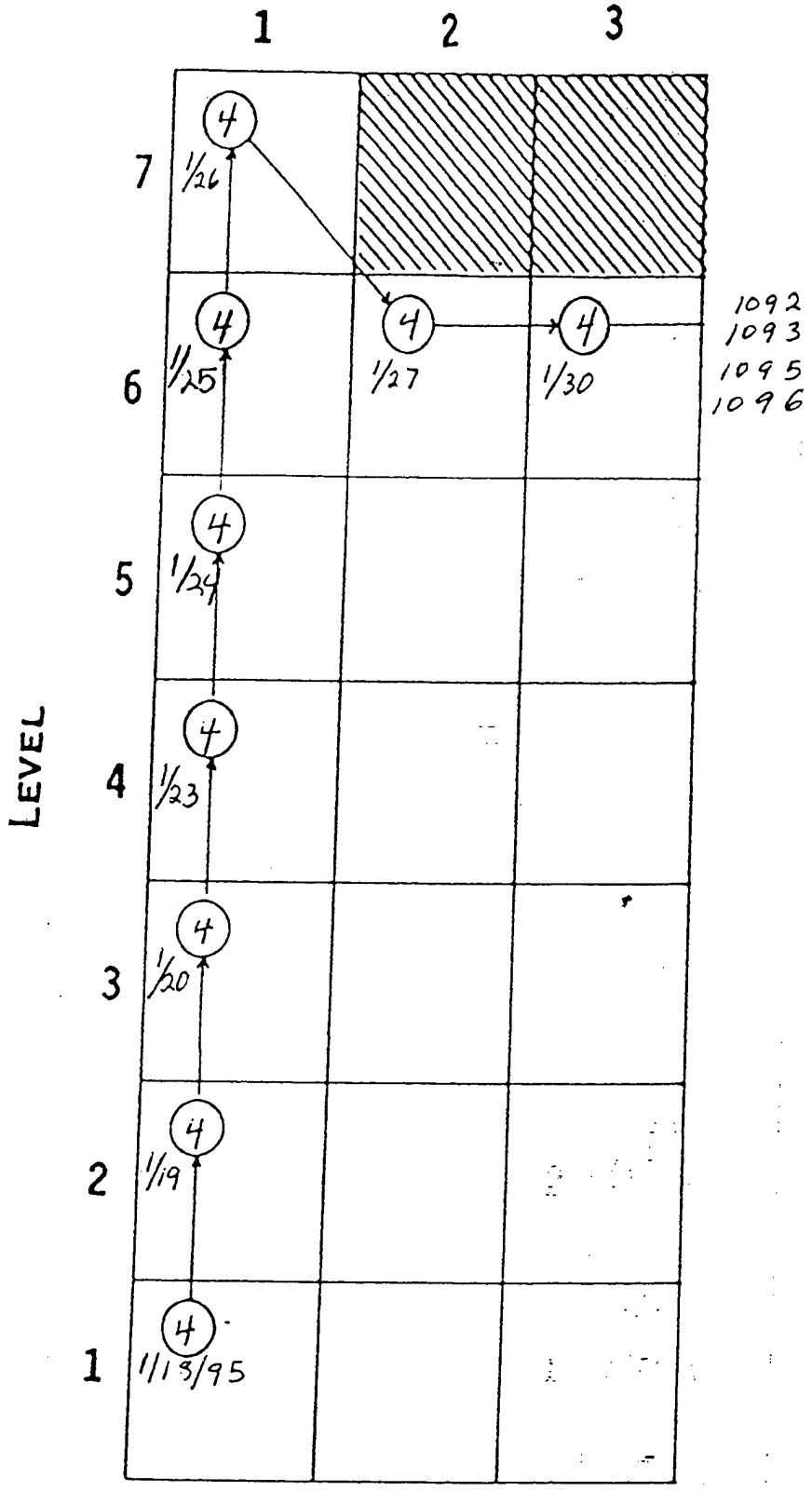
Appendix E-10. Exposure Matrix for Subjects 1062, 1063 and 1065, September 1994.



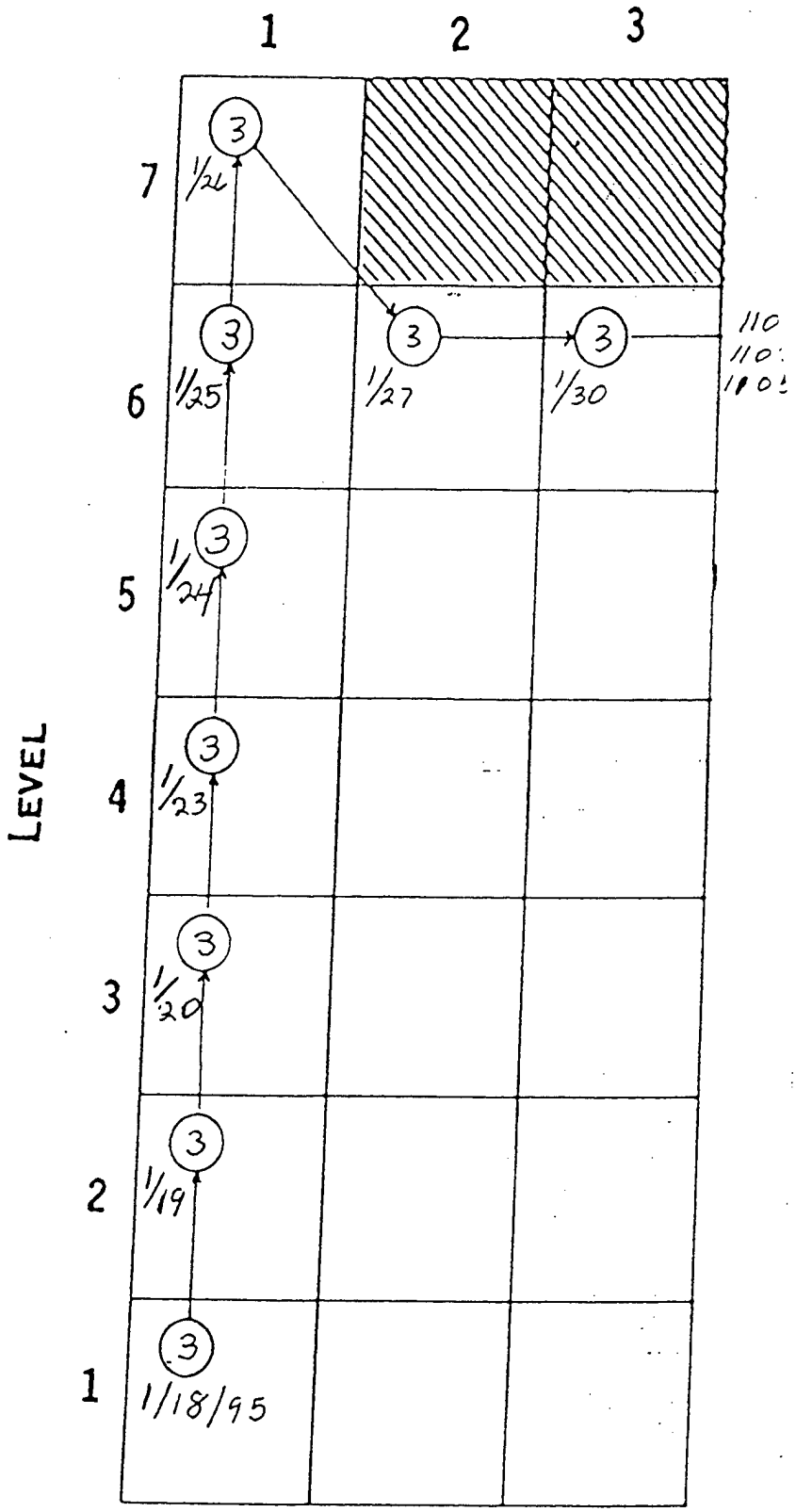
Appendix E-11. Exposure Matrix for Subjects 1072, 1073, 1075, and 1076, November 1994.



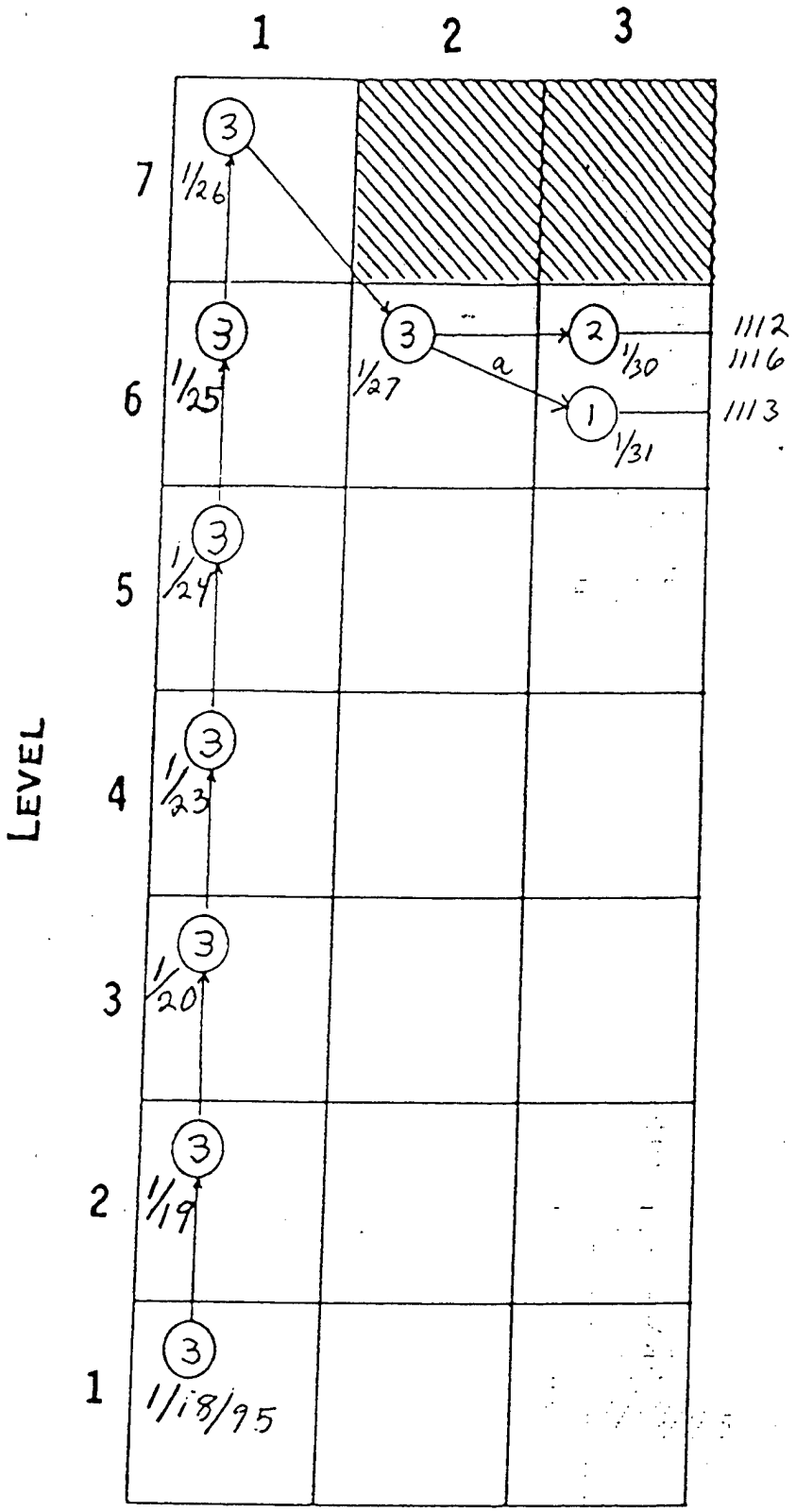
Appendix E-12. Exposure Matrix for Subject 1082, November 1994.



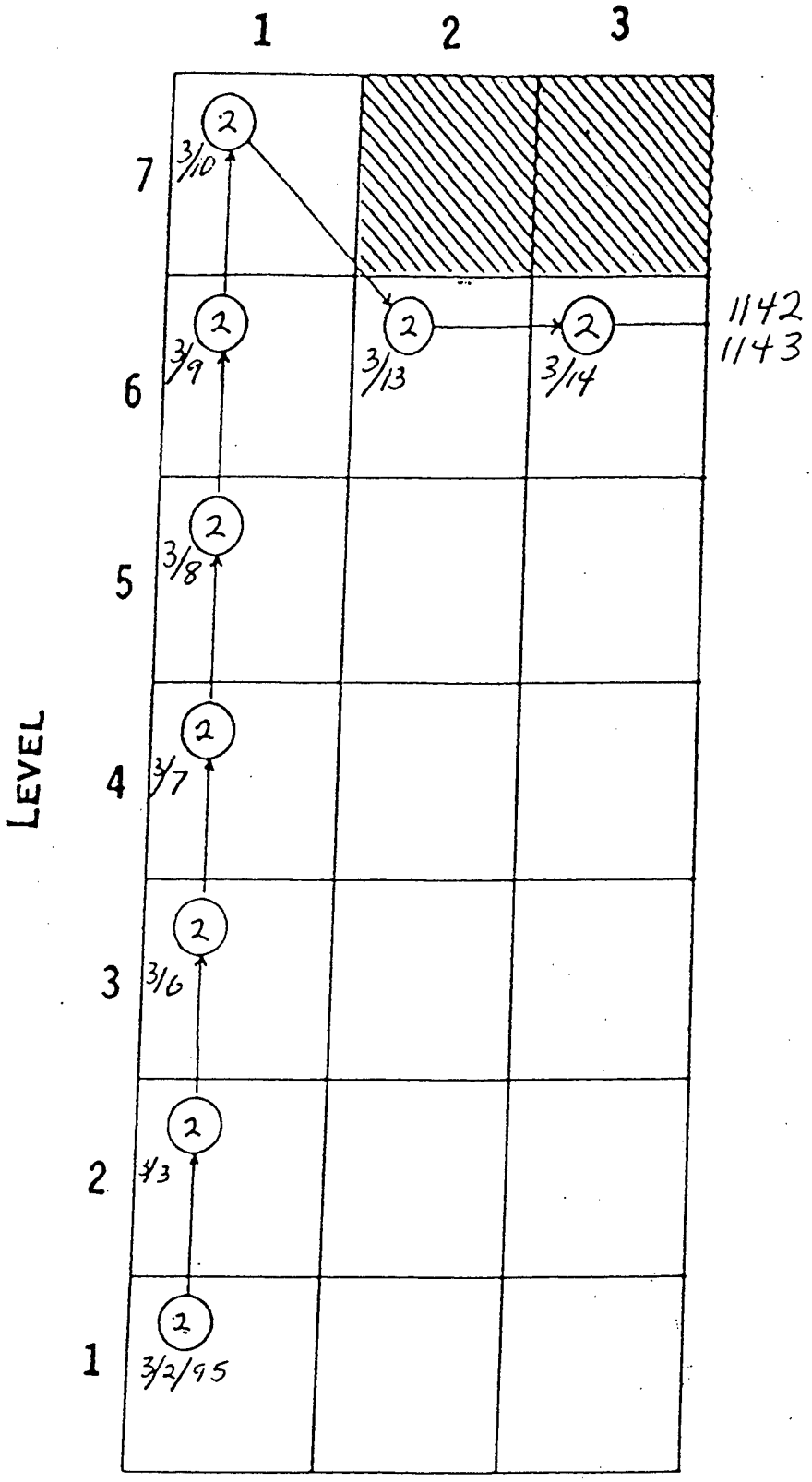
Appendix E-13. Exposure Matrix for Subjects 1092, 1093, and 1096, January 1995.



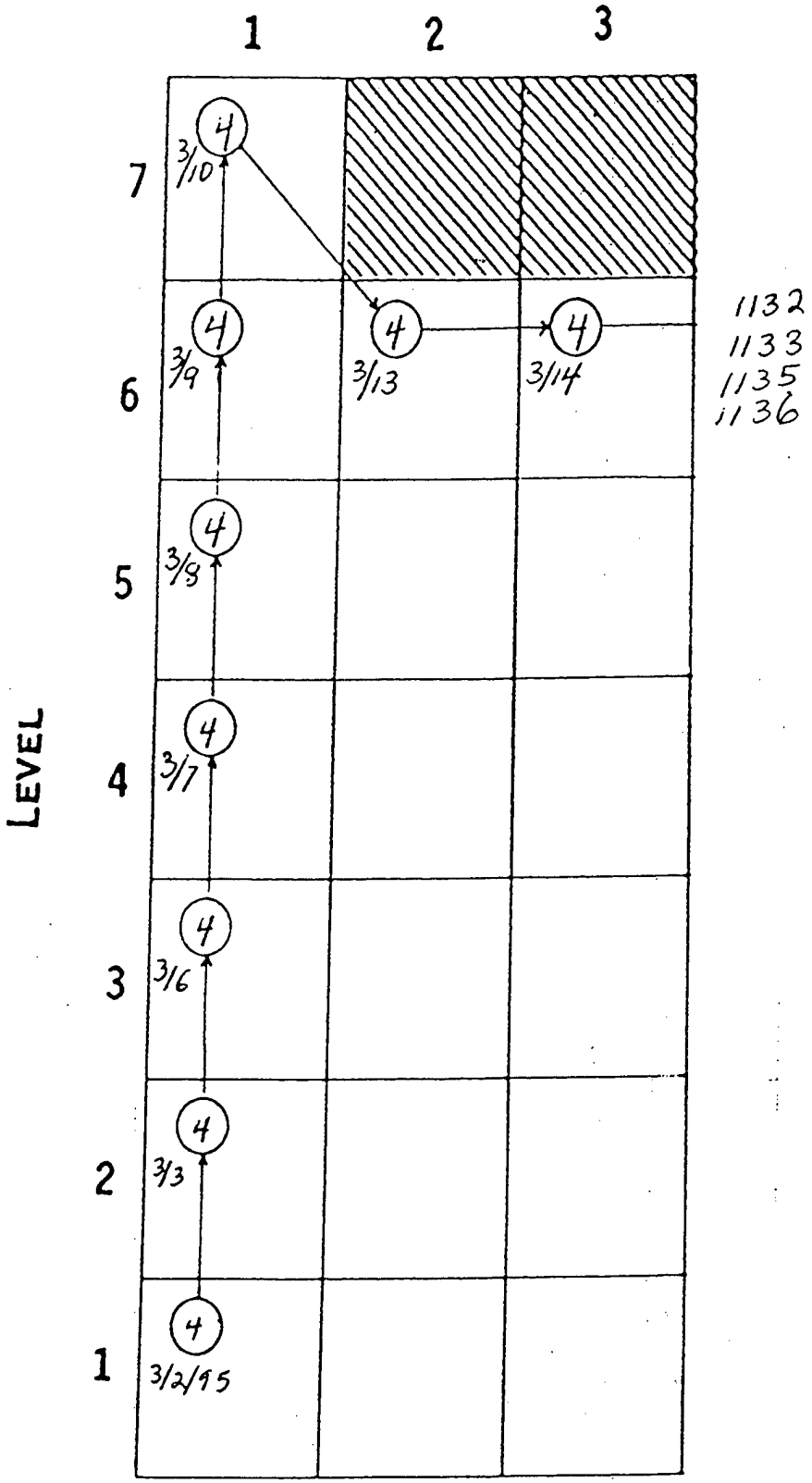
Appendix E-14. Exposure Matrix for Subjects 1102, 1105, and 1106, January 1995.



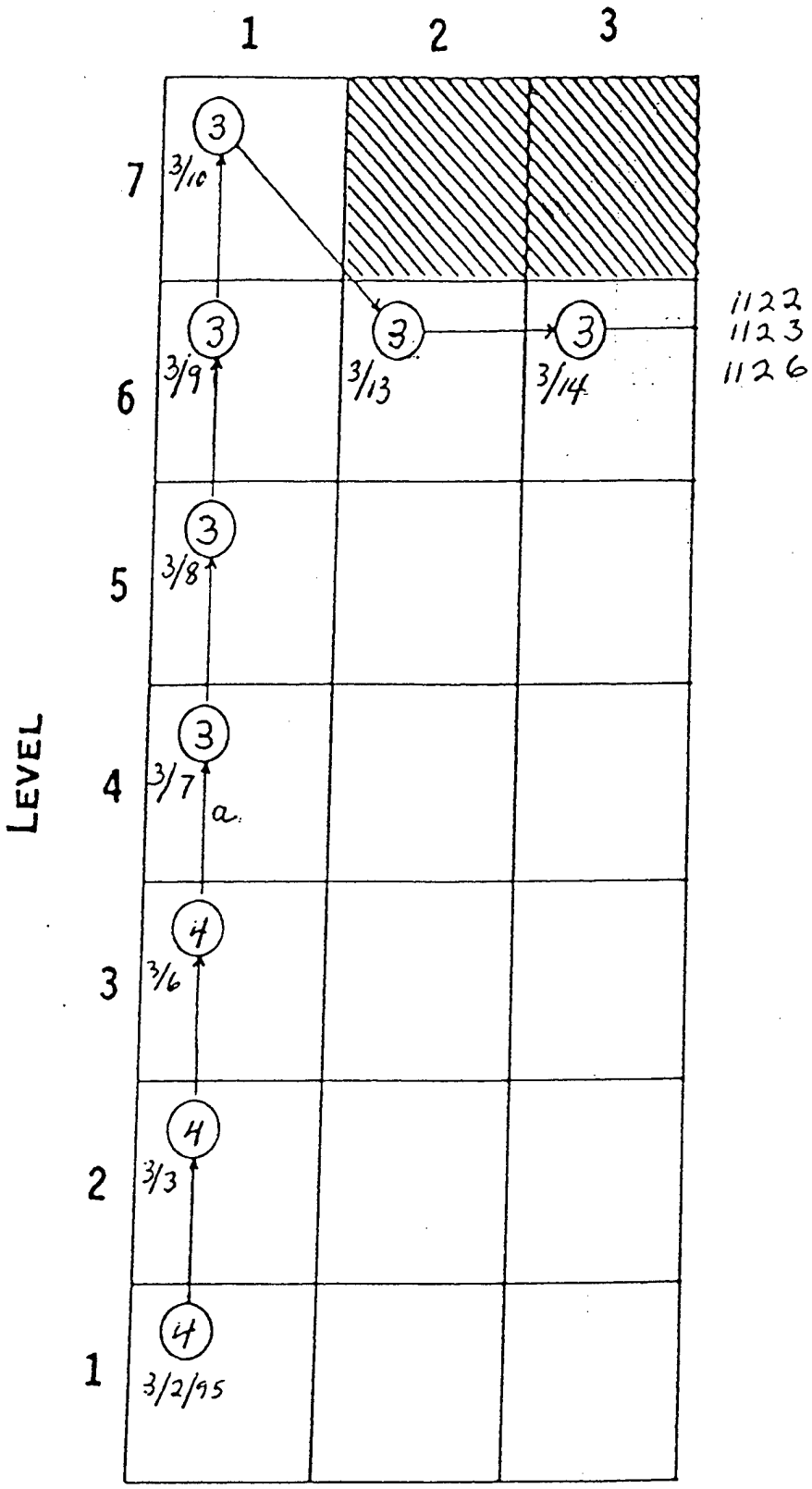
Appendix E-15. Exposure Matrix for Subjects 1112, 1113, and 1116, January 1995.
(Note: Subject 1113 had a positive guaiac on 1/30/95; negative on 1/31/95. Delayed one day.)



Appendix E-16. Exposure Matrix of Subjects 1142, and 1143, March 1995.

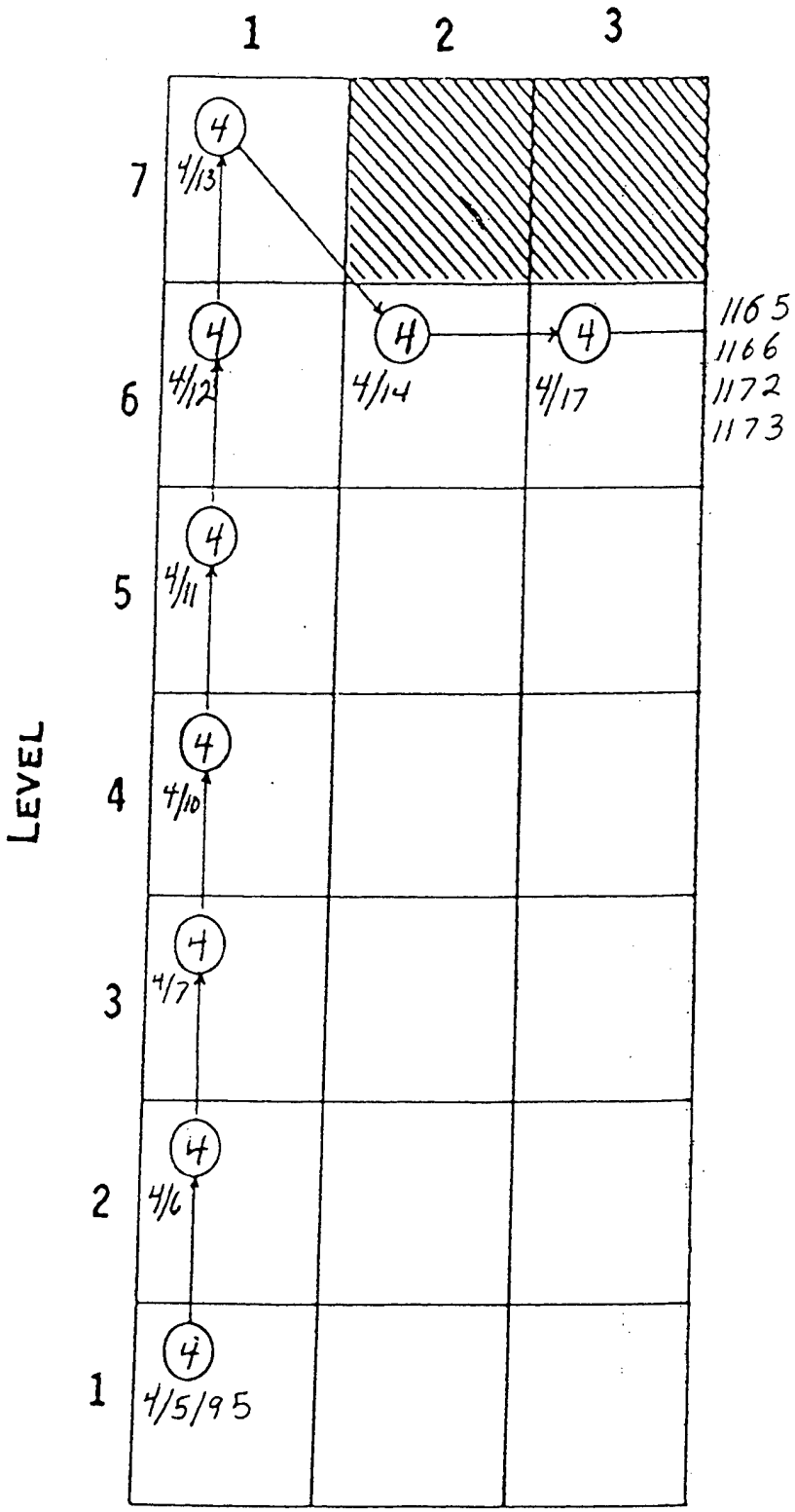


Appendix E-17. Exposure Matrix of Subjects 1132, 1133, 1135, and 1136, March 1995

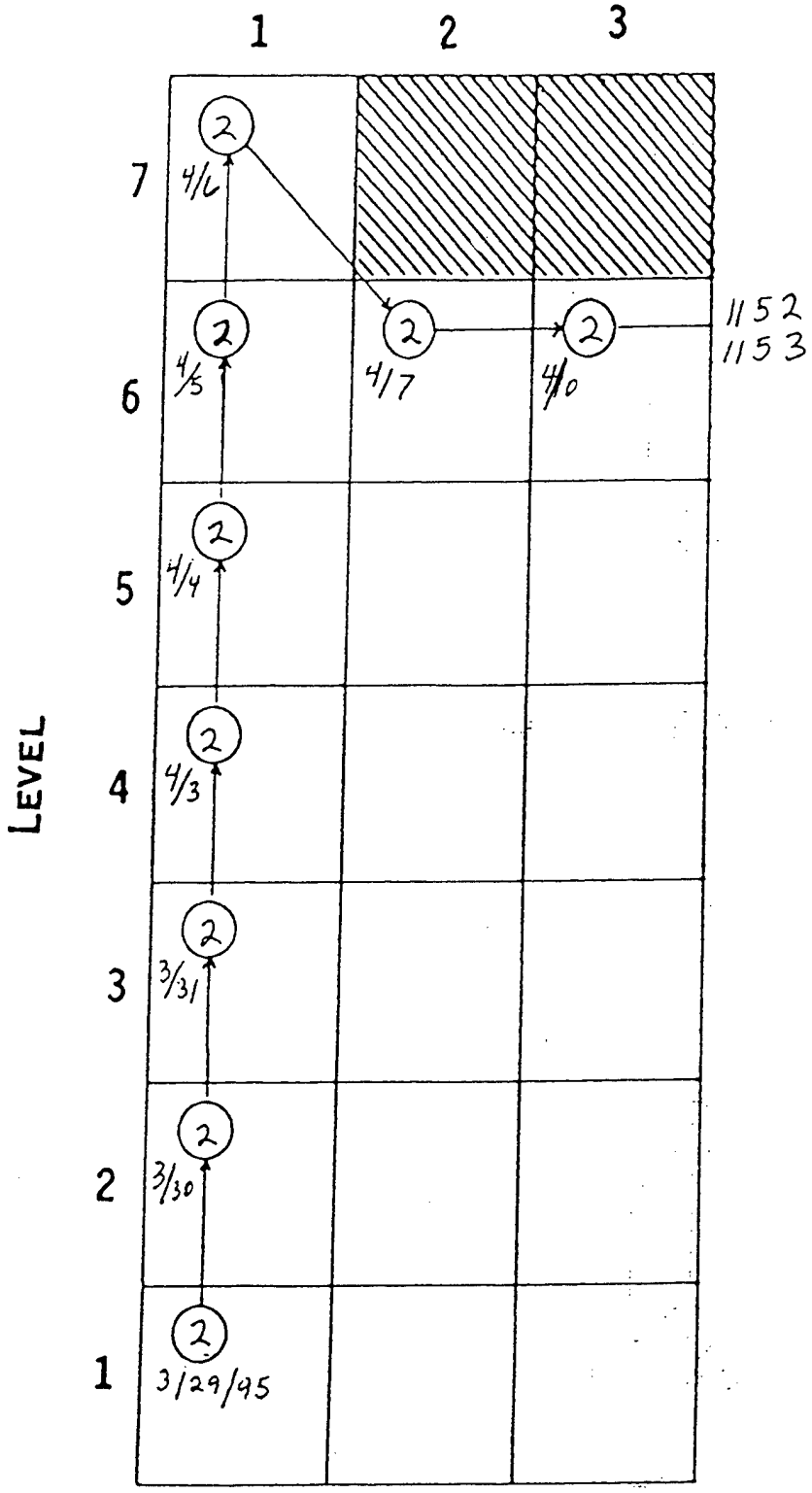


Appendix E-18. Exposure Matrix of Subjects 1122, 1123, 1125, and 1126, March 1995.

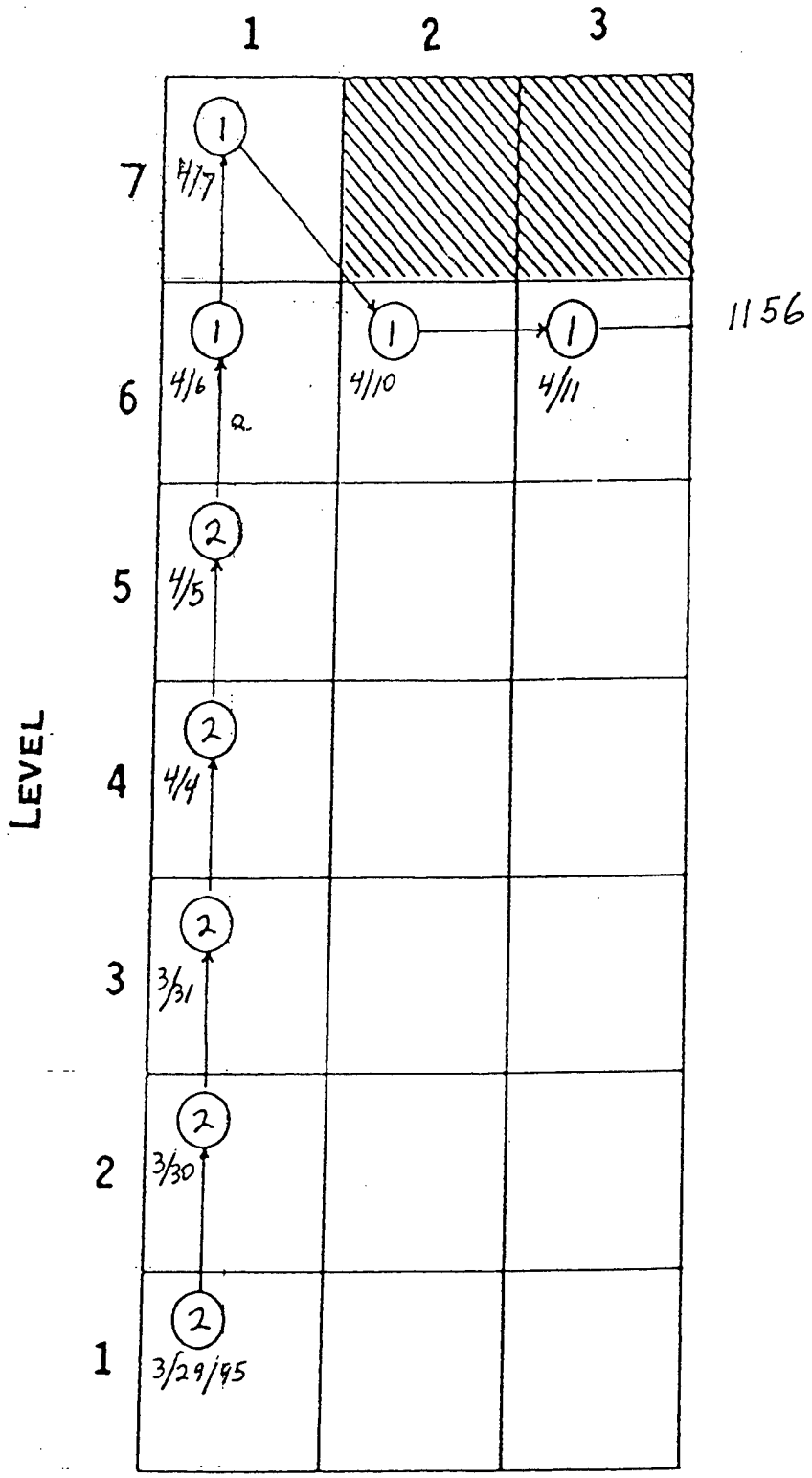
(Note: Subject 1125 was dropped after Level 3 because of his disclosure of a history of fainting and the fact that he had an episode the night of 6 March 1995.)



Appendix E-19. Exposure Matrix for Subjects 1165, 1166, 1172, and 1173, March/April 1995.

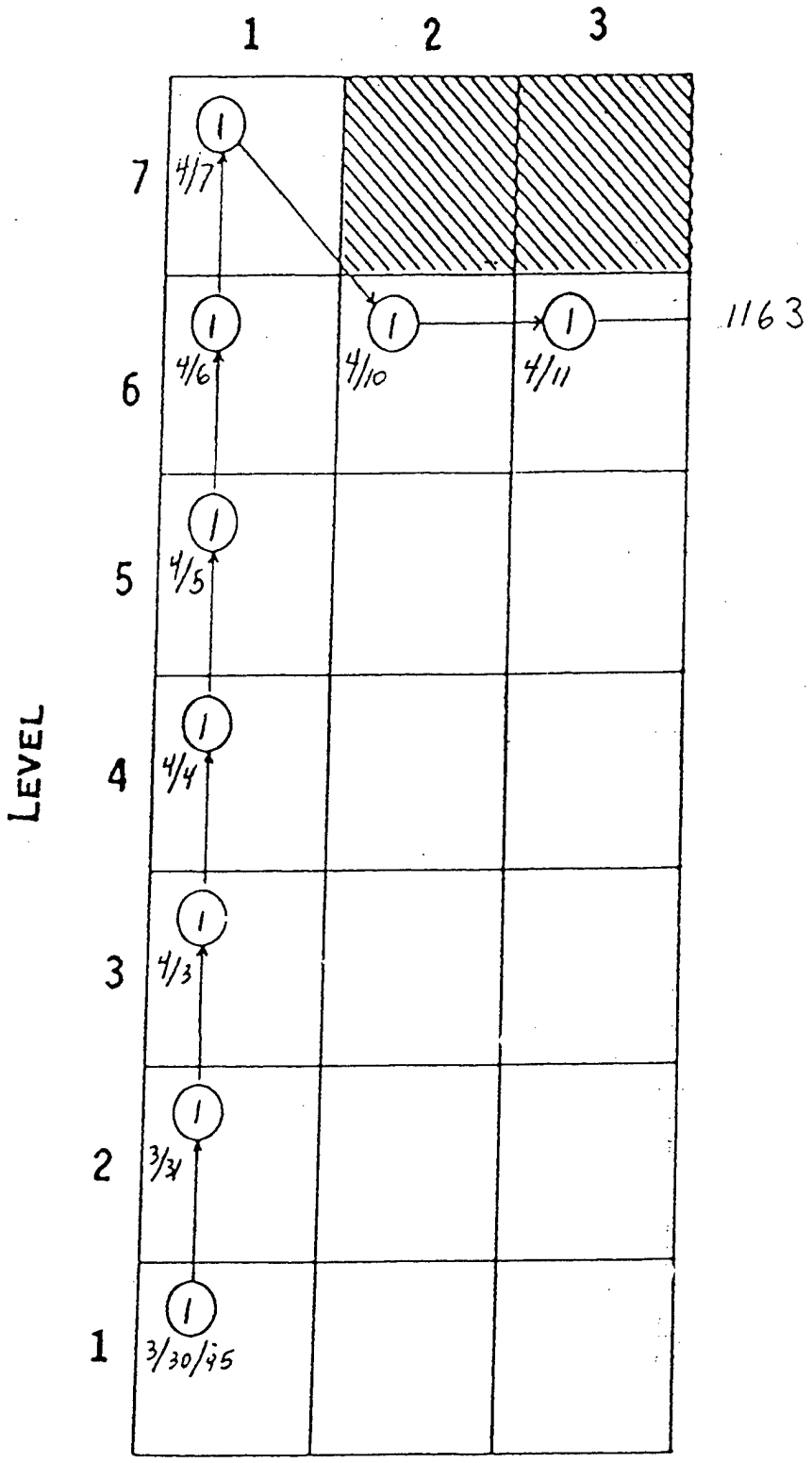


Appendix E-20. Exposure Matrix for Subjects 1152, and 1153, March/April 1995.

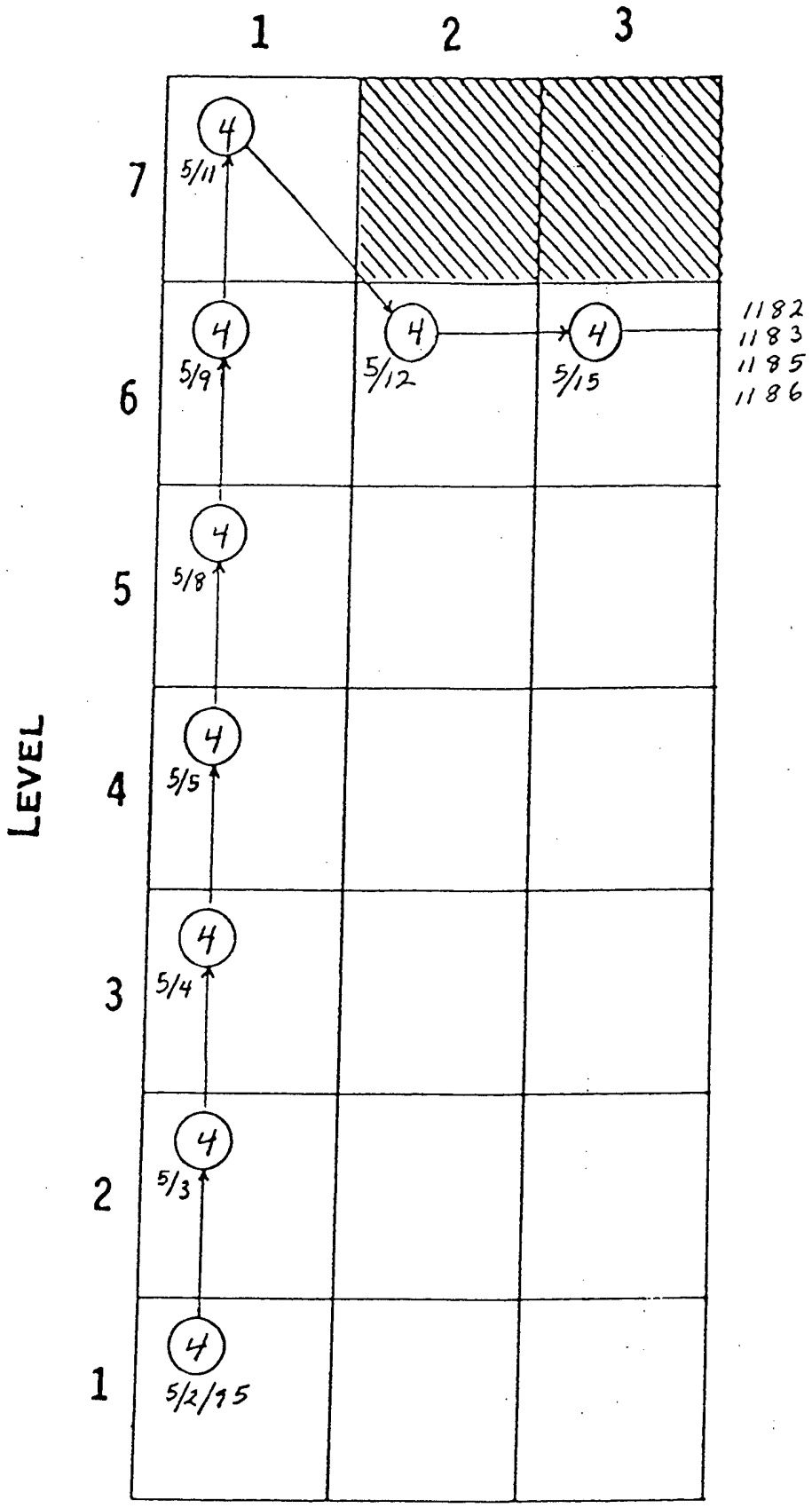


Appendix E-21. Exposure Matrix for Subject 1155 and 1156, March/April 1995.

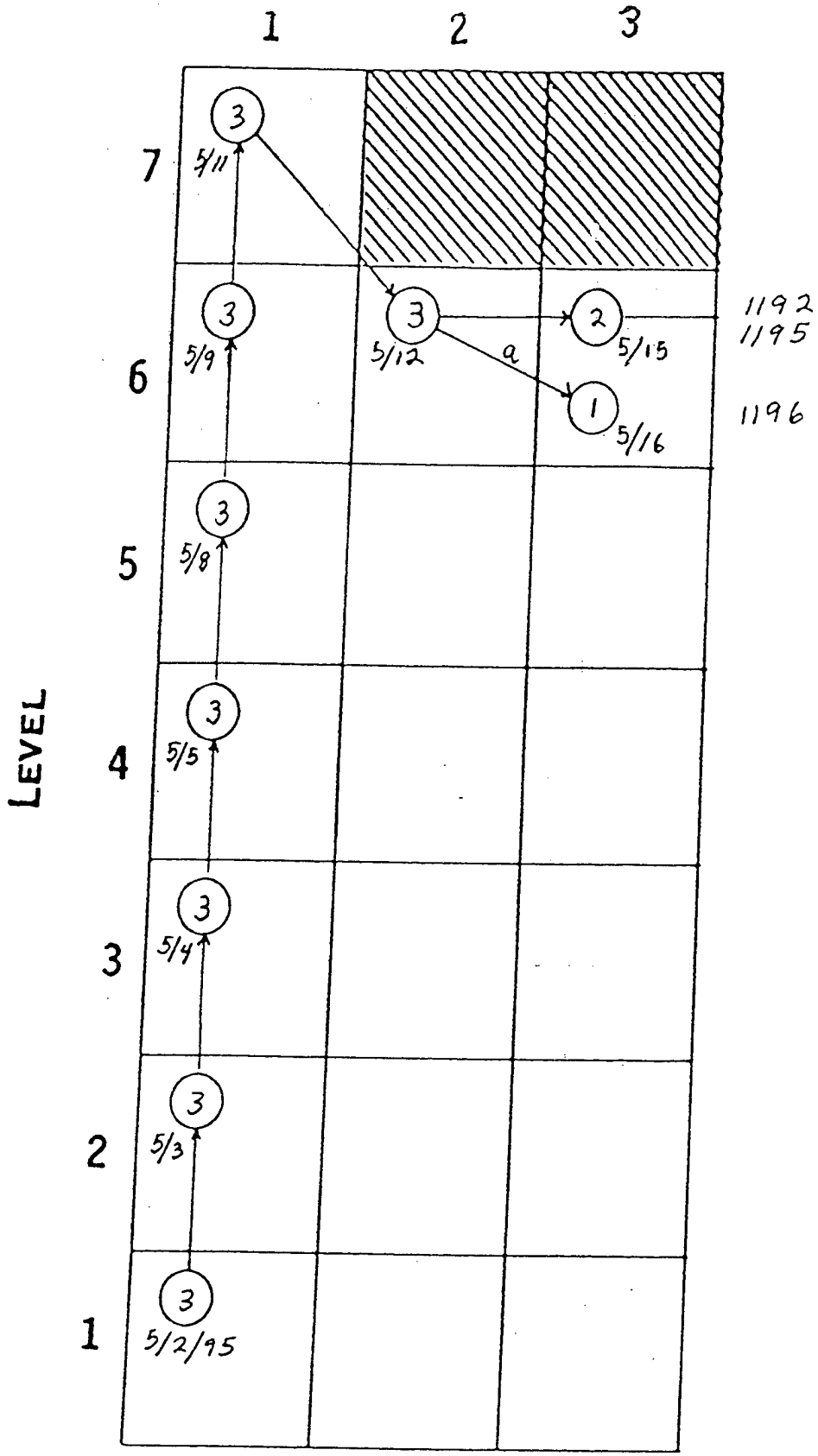
a. Subject 1155 elected to stop after Level 5.



Appendix E-22. Exposure Matrix for Subject 1163, March/April 1995.

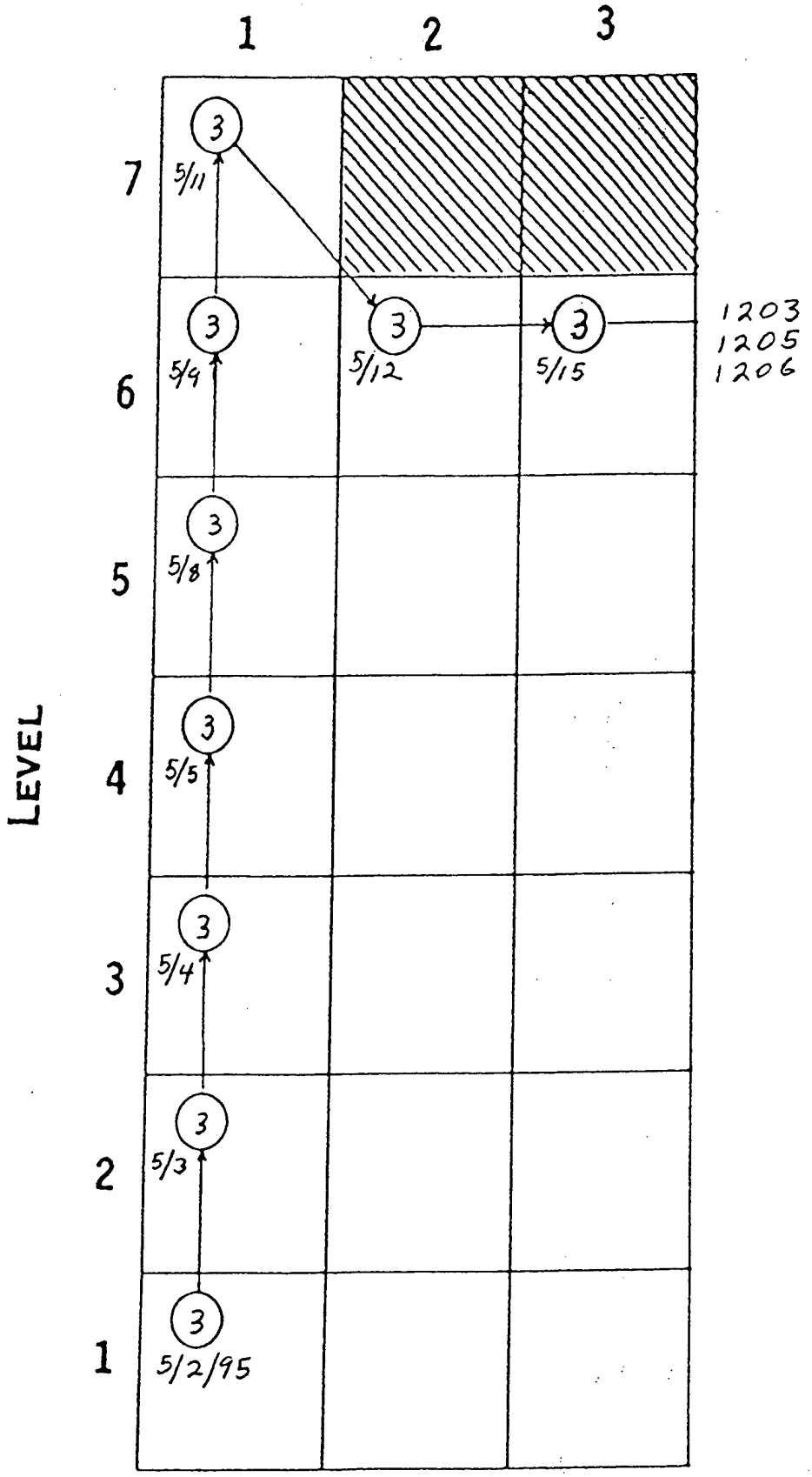


Appendix E-23. Exposure Matrix for Group 118, May 1995.

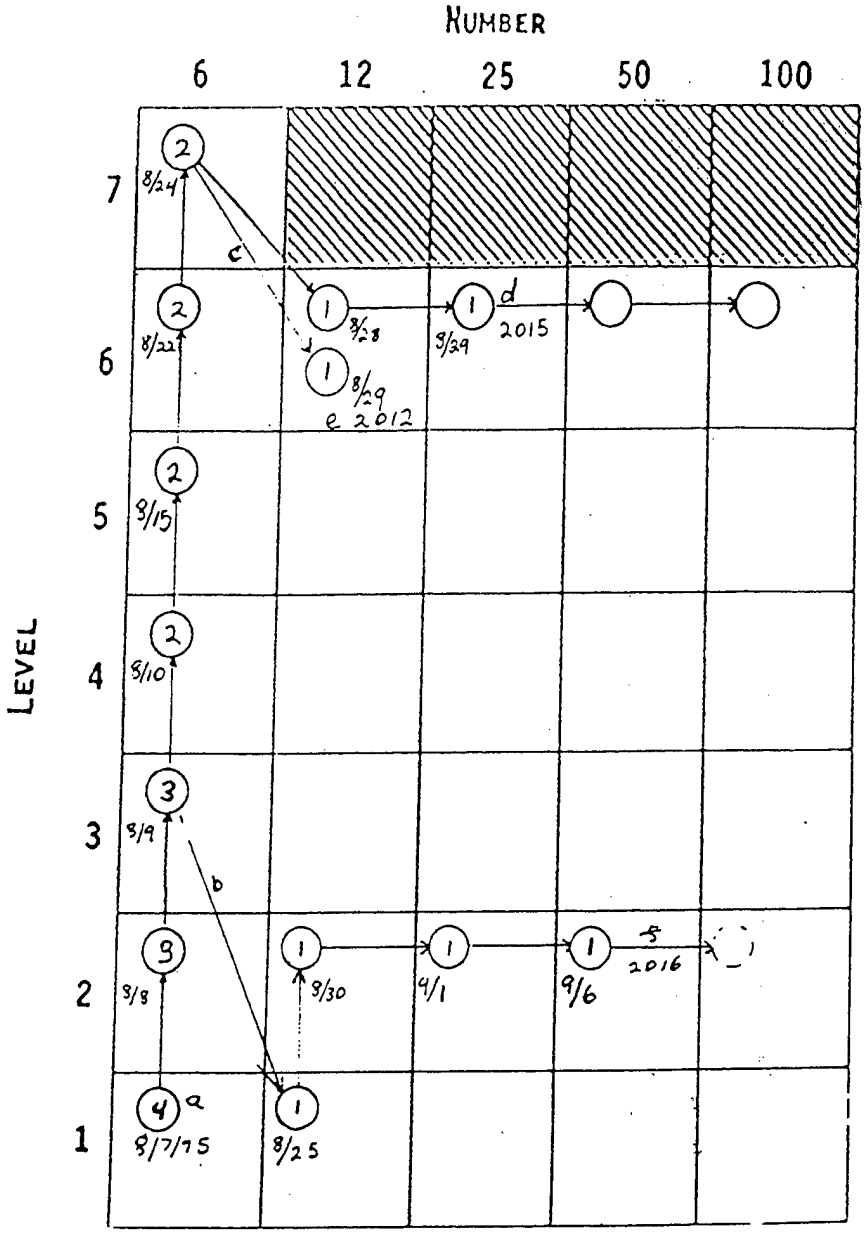


Appendix E-24. Exposure Matrix for Group 119, May 1995.

a. Subject 1196 had a positive guaiac on 15 may from eating raw meat. He was negative on 16 May.

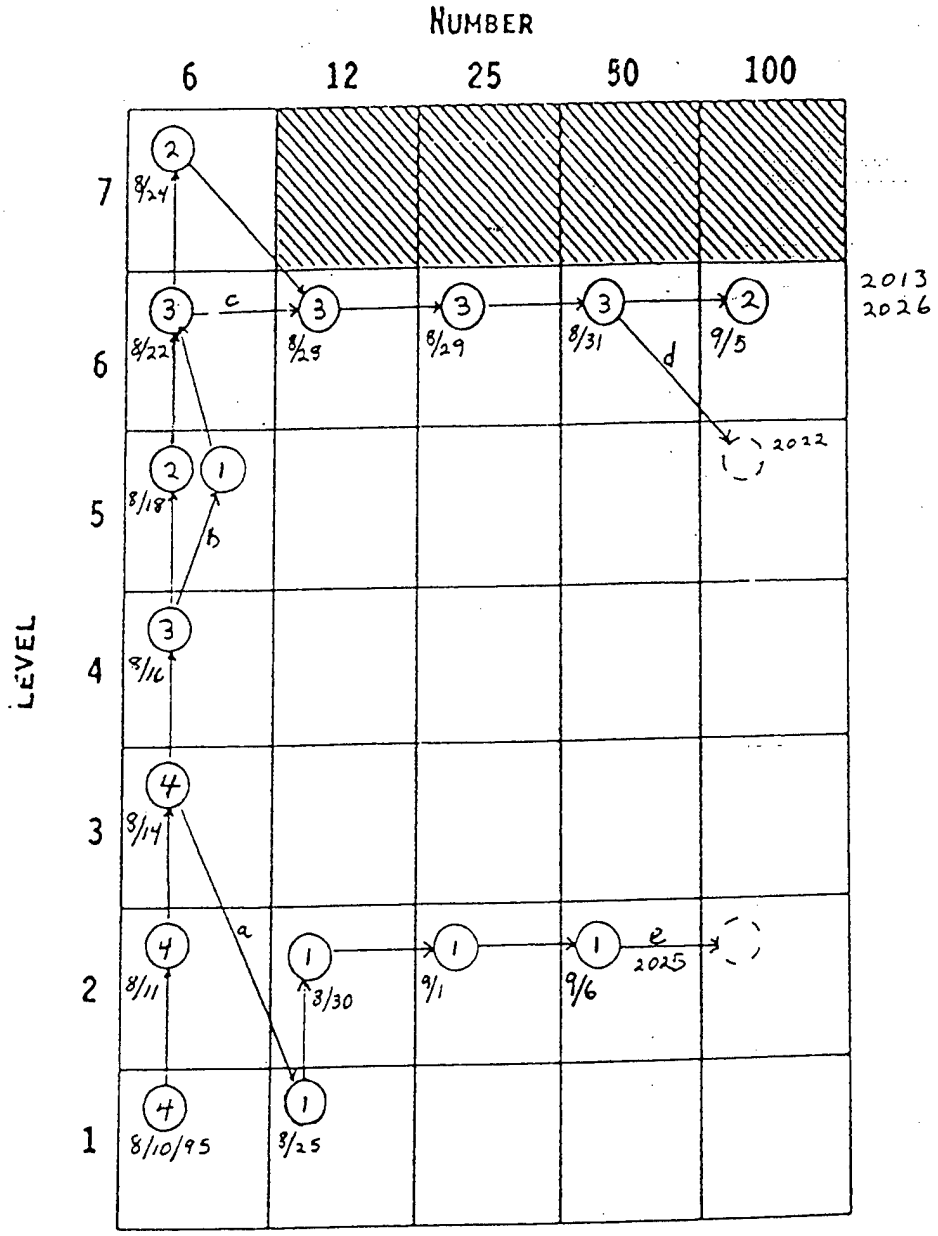


Appendix E-25. Exposure Matrix for Group 120, May 1995.



Appendix E-26. Exposure Matrix for Subjects 2012, 2015, and 2016, August 1995.

a. Subject 2013 was required to repeat condition 1/6 because of a mechanical failure of the audiometer (stepping attenuator) after his exposure to 1/6. He was moved to next group.
b. Subject 2016 was a failure at 2000 Hz after condition 3/6.
c. Subject 2012 was sick on 28 August, selected to go to Level 7.
d. Subject 2015 elected to stop after five shots of the 25 shots at Level 6.
e. Subject 2012 was an elective failure after condition 6/12.
f. Subject 2016 elected not to go to condition 2/100.



Appendix E-27. Exposure Matrix for Subjects 2022, 2013, 2025, and 2026, August 1995.

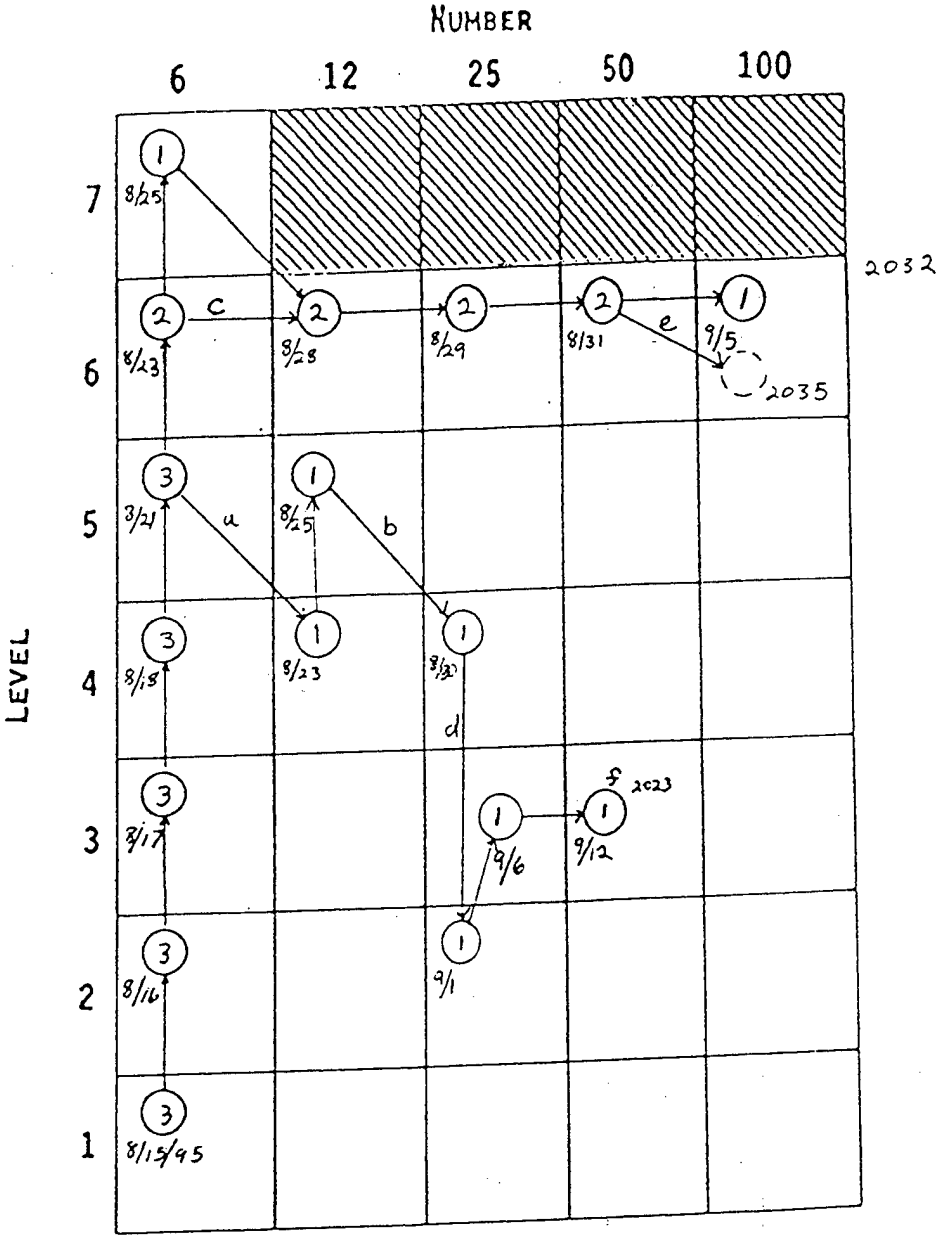
a. Subject 2025 was an audiometric failure with a TTS of 25 dB at 1 kHz at 20 minutes.

b. Subject 2013 was sick on 8/18/95 and was exposed to Level 5 on 8/21.

c. Subject 2013 elected not to go to Level 1.

d. Subject 2022 was a conditional failure after condition 6/50 with a TTS, of 17 dB at 2000 Hz. Because of time constraints, further testing was terminated.

e. Subject 2025 elected not to go to condition 2/100.



Appendix E-28. Exposure Matrix for Subjects 2032, 2023, and 2035, August 1995.

a. Subject 2023 was a conditional failure with a TTS of 18 dB at 3 kHz at the 20-minute post audiogram (TTS, was 14 dB).

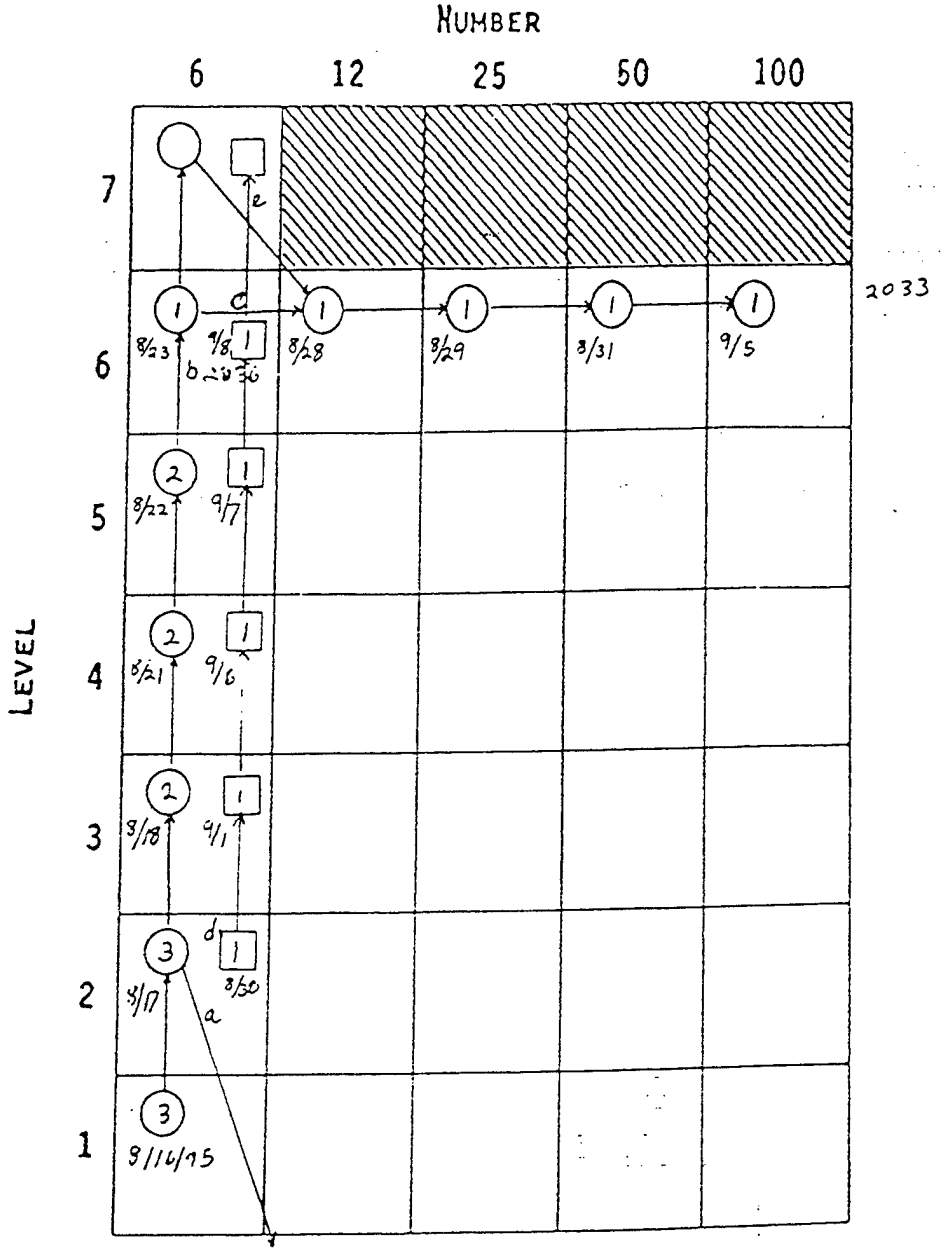
b. Subject 2023 was a conditional failure after condition 5/12 with a TTS of 22 dB at 3 kHz.

c. Subject 2035 elected not to go to Level 7.

d. Subject 2023 was a failure with a TTS,. Computer problems caused the delay.

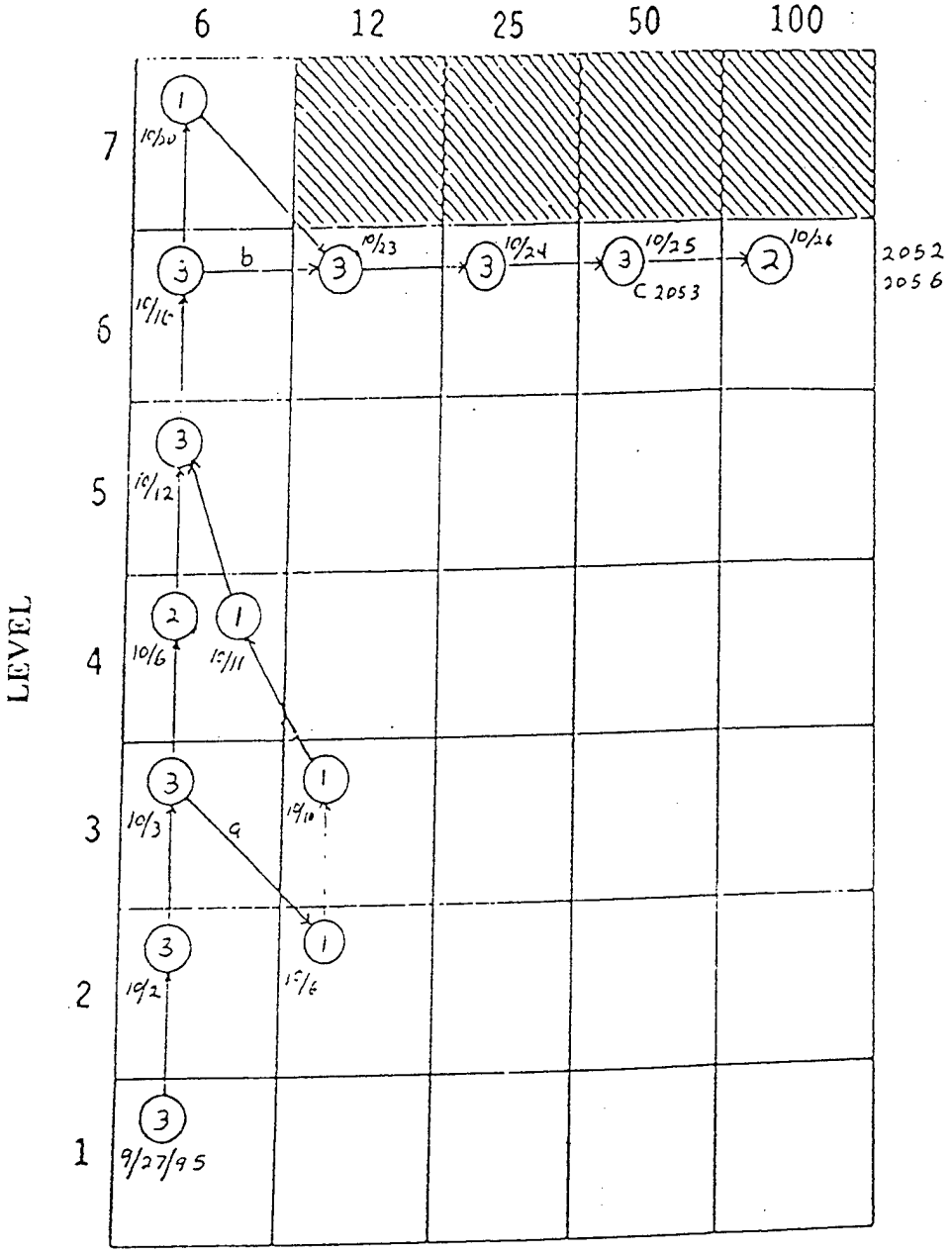
e. Subject 2035 was sick on 8/31/95.

f. Subject 2023 elected to stop further exposure after the first 12 shots of condition 3/50. His ears started ringing after shot 10 and became worse after shot 12. No TTS occurred. Considered an elective failure after condition 3/25.



Appendix E-29. Exposure Matrix for Subjects 2042, 2033, and 2036, August 1995.

a. Subject 2042 was a failure with a TTS of 20 dB at 2 minutes and 28 dB at 1 hour.
b. Subject 2036 elected to stop further exposures.
c. Subject 2033 elected not to go to Level 7.
d. Subject 2042 started with level 2 protection on 30 August.
e. Subject 2042 was an elective failure after condition 6/6, second-level hearing protection.

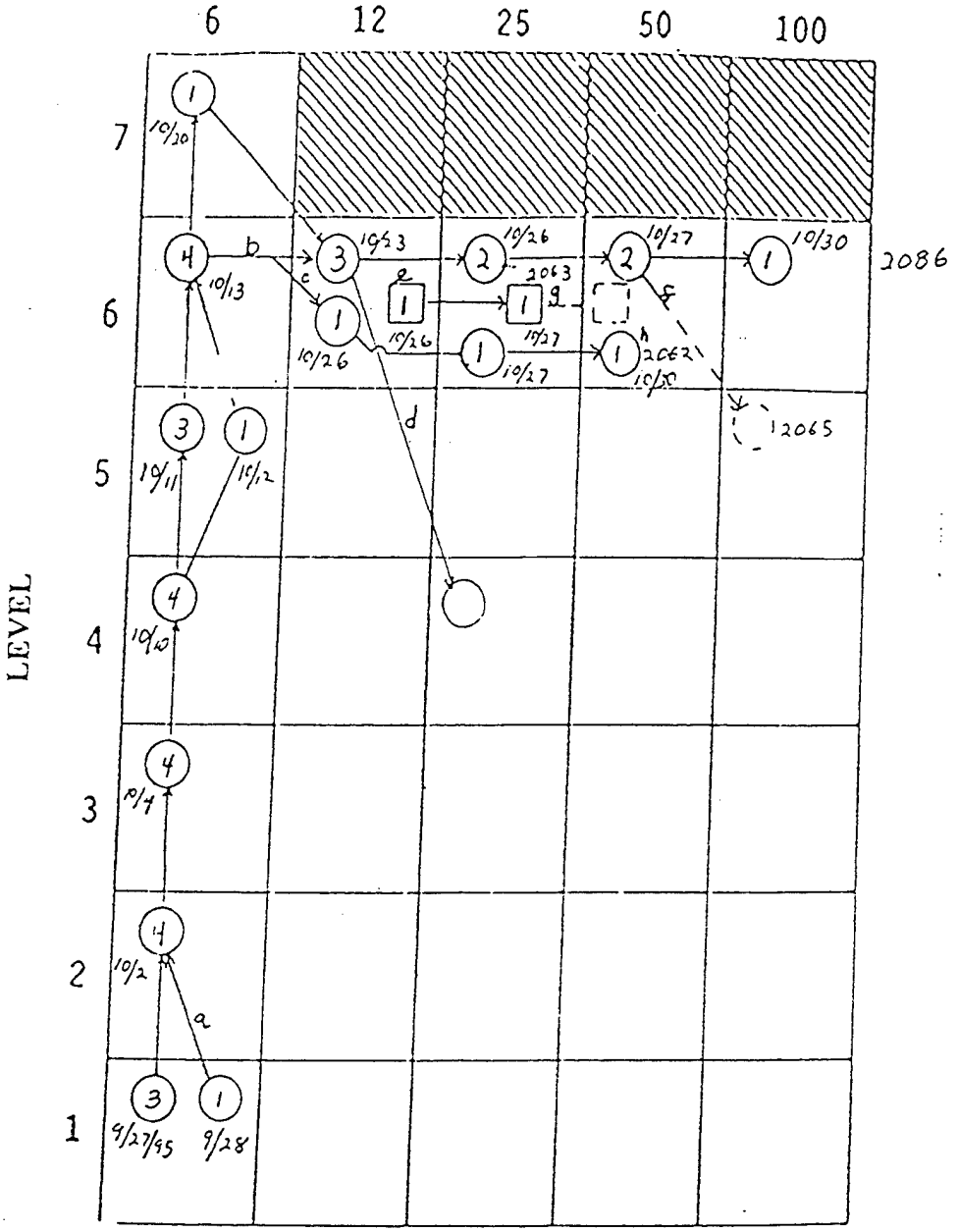


Appendix E-30. Subject Nos. 2052, 2053, and 2056, September-October 1995.

A. Subject 2056 was a conditional failure with a TTS of 23 dB at 6000 Hz.

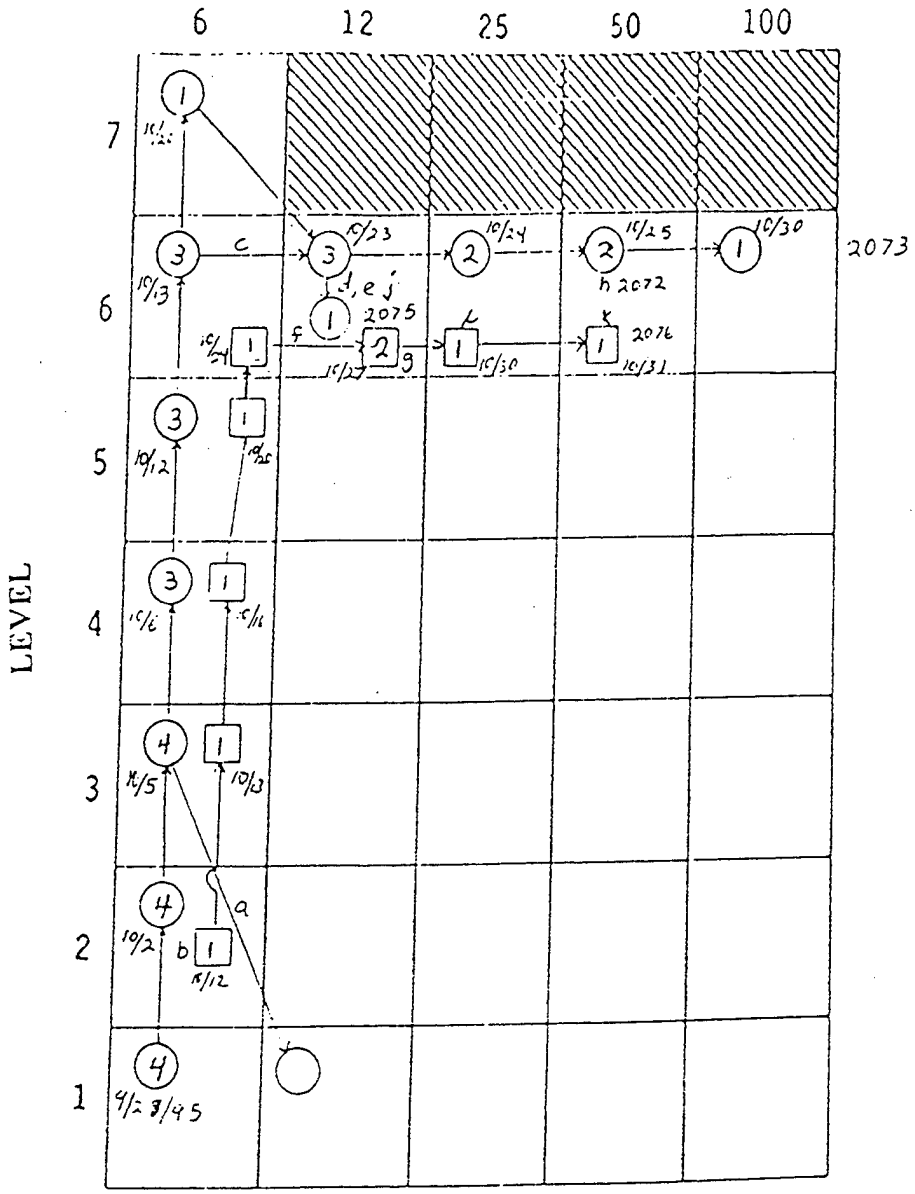
B. Subjects 2053 and 2056 elected not to go to Level 7.

C. Subject 2053 elected not to go to condition 6/100.



Appendix E-31. Subject Nos. 2062, 2063, 2065, and 2086, September-October 1995.

A. Subject 2065 delayed 1 day due to needing his ears cleaned.
B. Subject 2062, 2063, and 2065 elected not to go to Level 7.
C. Subject 2062 had strep throat on 23 October.
D. Subject 2063 was an auditory failure with a TTS_2 of 28 dB at 1 kHz.
E. Subject 2063 started second-level hearing protection.
F. Subject 2065 was a conditional failure with a TTS_2 of 19 dB at 4 kHz and a TTS_{20} of 22 dB at 2 kHz. Subject elected not to go to condition 5/100.
G. Subject 2063 was an elective failure to condition 6/50 with second-level protection. Cited headaches caused by the blast.
H. Subject 2062 was an elective failure for condition 6/100.



Appendix E-32. Exposure Matrix for Subject Nos. 2072, 2073, 2075, and 2076, September-October 1995.

A. Subject 2076 was an audiometric failure with a TTS_2 of 38 dB at 4 kHz and 22 dB at 8 kHz.

B. Subject 2076 started second-level hearing protection with E.A.R.® foam plugs.

C. Subjects 2072 and 2075 elected not to go to Level 7.

D. Subject 2075 came off the pad early because his ringing kept getting worse after shot 3. He came off after shot 8. He did not have a trace of TTS, thus, he was required to redo condition 6/12.

E. Subject 2075 was a conditional failure with a TTS_2 of 15 dB at 4 kHz

F. Subject 2076 elected not to go to Level 7 with second-level hearing protection.

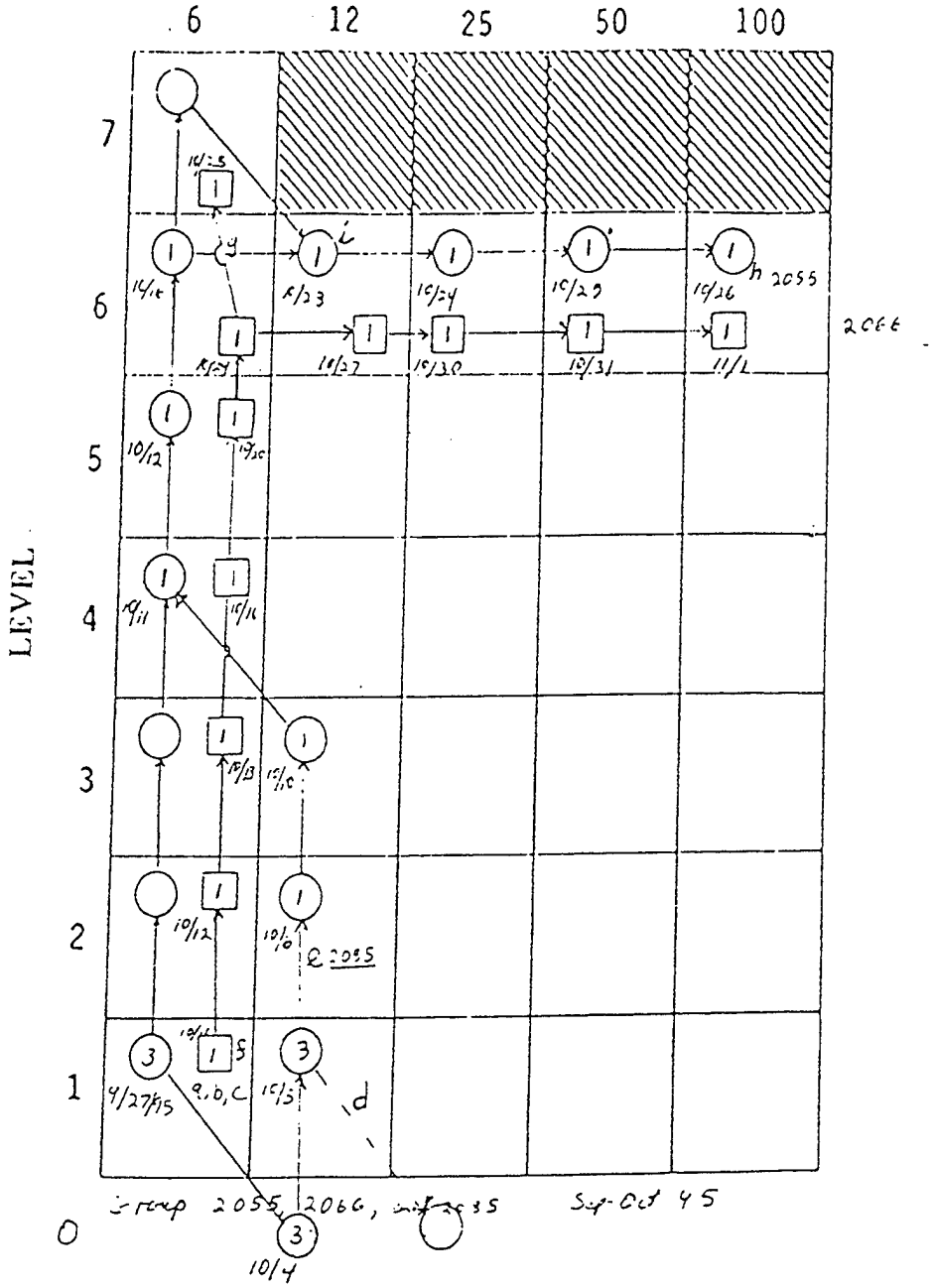
G. Subject 2075 began second-level hearing protection.

H. Subject 2072 elected not to go to condition 6/100.

I. Subject 2076 was taken off the pad after 20 shots because of a sinus headache that kept becoming worse with each blast.

J. Subject 2075 elected to stop further exposure both to 6/25 with second-level hearing protection or condition 5/25 with first-level hearing protection.

K. Subject 2076 came off the pad at 40 shots because of a sinus headache that started at shot 10 and increased until shot 20, then stayed constant. Elected not to go to condition 6/100.



Appendix E-33. Subjects 2055, 2066, and 2085, September-October 1995.

A. Subject 2055 was a conditional failure with a TTS_2 of 16 dB at 2000 Hz.

b. Subject 2066 was a conditional failure with a TTS_2 of 21 dB at 2000 Hz.

c. Subject 2085 was a conditional failure with a TTS_2 of 18 dB at 8 kHz.

d. Subject 2066 was a conditional failure with a TTS_2 of 16 dB at 2 kHz and a TTS_{30} of 17 dB at 3 kHz.

E. Subject 2085 was administratively dropped from the study for a behavior problem (skipping out from his barracks several times at night without permission).

F. Subject 2066 started second-level hearing protection (E.A.R.® Foam plug) on 10/11/95.

G. Subject 2055 elected not to go to Level 7.

H. Subject 2055 elected to stop further exposure after 44 shots of condition 6/100. He adjusted his plug once, yet his ringing in his ear kept increasing.

I. Subject 2055 felt his earplug loosen, so he came off the pad after shot 9 of the 12 shots.

APPENDIX F. FORMAT FOR CD-ROM MEDIA

FORMAT FOR CD-ROM MEDIA

It is our intent to make the basic data available for other analyses. The method for providing the data and results will be via the CD-ROM media. The disk will contain all the data bases generated by the research project. The disk will also include sample waveforms in the original TDR format. So the reviewer can view the blast waves, a simple graphical program VIEWER was developed and placed on the disk. The program will allow the user to view the waveforms with limited zooming functions. The standard calculations will be displayed. The data bases included on the CD-ROM are as follows:

1. **Audiology**

   a. Data base of all audiometric tests
   b. Baseline audiograms (occluded and unoccluded data bases)
   c. Temporary Threshold Shift (TTS) data

2. **Otoacoustic Emissions**

3. **French Audioscan**

4. **Performance Aptitude Battery Test**

5. **Physical Ear Attenuation Test**

6. **Medical Data**

7. **Blast Records**

8. **Sample TDR Records**

   70 records of sample waveforms from the Firing from a Bunker Study and 61 records of sample waveforms from the Nonlinear Earplug Study.

9. **VIEWER.EXE**

   Program to view the TDR files.

10. **Logbook Records**

Comments recorded about subjects during the study.

11. **Lovelace Prestudy and Post Study Audiograms**
Audiograms done at the Lovelace Medical Center.

All data bases are in DBASE IV FILES or Microsoft Access or both.

It is assumed that the CD-ROM will be available from the U.S.Army Medical Research and Materiel Command, Fort Detrick, Frederick, MD.

APPENDIX G. SUBJECT DEMOGRAPHICS

There were a total of 86 subjects that participated in the studies reported herein. The breakout of these subjects as compared to the U.S. Army as a whole is as follows:

Race	Number	Percent	Percent in Army*
Caucasian	49	57	59
Black	20	23	30
Hispanic	12	14	5
Other	5	6	6

* Defense '94 Almanac, Issue 5, Department of Defense.

APPENDIX H. WAVEFORM STATISTICS

A. INTRODUCTION

During the course of the studies since June 1994, thousands of blast measurements were made. This appendix summarizes the high-explosive charge weights used to produce such blasts, the typical waveforms of each blast level, and finally, a summary of the blast parameters for each blast level. It should be remembered that the entire data base may eventually be available on a CD-ROM disk (see Appendix G).

B. CHARGE WEIGHTS

Table H-1 lists the charge weight of C-4 (or primacord where indicated) for all freefield distances and the firing from an enclosure simulations. The nonlinear plug study reported herein used the 3-m distance.

Table H-1

Charge Weights Used for the Various Simulations at the BOP Test Site, 1989-1995

Level	Distance				
	1 M	3 M	5 M(A)[a]	5 M(B)[b]	Bunker
Charge Weight (C-4 or Det Cord), lb					
1	0.05*	0.10*	0.23	0.23	0.013*
2	0.10*	0.21	0.43	0.39	0.026*
3	0.21	0.40	0.77	0.71	0.051*
4	0.40	0.81	1.37	1.27	0.106
5	0.81	1.50	2.45	2.30	0.225
6	1.75	1.75	4.20	3.90	0.450
7	3.00	3.20	3.20	N/A	0.540

* Det cord.

[a] For the 3-m distance, the distance of the subjects from the lip of the tube was 2.13 m (7 ft) for Levels 1 through 5 and 1.68 m (5.5 ft) for Levels 6 and 7.

[b] For the 5-m distance, the A-weights were used for 25 or less shots and B-weights were used for 50 or more shots.

C. TYPICAL WAVEFORMS

1. Firing from a Bunker Simulator

Typical waveforms for each of the seven blast levels are shown in Figures H-1 through H-7. Table H-2 is a summary of the blast parameters for each individual example. These levels are for the reference gauge on the front (east) wall of the enclosure.

2. Nonlinear Plug Study

Typical waveforms for each of the seven blast levels as measured at the head position are shown in Figures H-8 through H-17. Table H-3 is a summary of the blast parameters of each individual waveform.

D. SUMMARY OF BLAST PARAMETERS

1. Firing from a Bunker Simulator

Table H-4 is a summary of the blast parameters as measured at the east wall reference gauge for each blast level. The reader should be cautioned that some parameters that work well for freefield waveforms have questionable utility for complex waves. For instance, the A-duration of the first peak virtually tells the user nothing about the waveforms shown in Figures H-1 through H-7.

2. Nonlinear Plug Study

Table H-5 is a summary of the blast parameters as measured at the subject's head position without the subject present.

E. CALIBRATION OF THE HEAD POSITIONS FOR THE FIRING FROM A BUNKER SIMULATION

Because placing gauges at the head position with the subjects present was not possible, there were special calibration measurements (Tables H-6 through H-8) made at the center of the head position of the subjects. Using regression analysis (Figure H-15), there was approximately a 3-dB difference between the levels of the east wall gauge and the levels of the average of the gauges at the head position. A 3-dB correction was subtracted from the east wall gauge values to establish the values shown in Figure III-1. Figures H-16 and H-17 are typical waveforms for the head position for Level 6.

Table H-2.Individual Parameters for the Waveforms of Figures H-1 through H-7.

			Max Peak		DURATIONS				IMPULSE		ENERGY (SEL)		
	Charge				A	B	C	D	A	Max	Total	A Weighted	P Weighted
Intensity	Weight	Test ID	(kpa)	(dB)	(ms)				(kpa*ms)		(SEL)		
1	6.4 g	1101	5.66	169.05	0.86	289.66	160.37	77.30	2.45	314.65	132.16	130.51	129.60
2	12.5 g	1104	6.99	170.90	2.42	327.97	144.98	120.11	6.42	10.39	134.63	133.25	132.35
3	23.0 g	1105	10.06	174.05	2.06	279.29	106.55	95.62	9.02	135.36	137.41	134.43	133.61
4	50.0 g	1146	17.78	179.00	1.07	224.65	104.53	64.30	10.09	111.24	141.27	138.79	138.01
5	102.0 g	1152	26.94	182.61	3.92	247.28	85.45	128.37	48.09	314.17	143.98	141.44	141.27
6	203.0 g	1095	37.49	185.48	1.37	163.06	75.34	55.58	19.85	89.99	145.76	142.01	141.12
7	245.0 g	1092	42.66	186.60	3.08	209.41	68.70	54.86	48.74	659.59	147.42	143.22	142.29

Table H-3.Individual Parameters for the Waveforms of Figures H-8 through H-14.

			Max Peak		DURATIONS				IMPULSE		ENERGY (SEL)		
	Charge				A	B	C	D	A	Max	Total	A Weighted	P Weighted
Intensity	Weight	Test ID	(kpa)	(dB)	(ms)				(kpa*ms)		(SEL)		
1	45.3 g	1357	9.92	173 93	1.34	28.26	6.02	0.71	5.12	68.67	129.47	123.71	123.25
2	95 3 g	1363	15.57	177 85	1.47	15 80	6.90	0.74	8.42	166.49	129.99	127.92	127.37
3	181.0 g	1366	22.01	180 85	1.45	15 24	5.56	0.79	12.82	70.31	131.63	130.29	129.91
4	367.0 g	1371	34 04	184 64	1.47	19.50	6.66	8.17	20.40	20.40	136.03	134.43	133.82
5	680.0 g	1386	60.32	189 61	1.47	17.18	4.10	0.74	32.09	32.09	139.92	137.93	137.33
6	794 0 g	1381	69 01	190 78	1.56	13.52	4.46	0.59	34.15	100.10	140.48	138.87	138.55
7	1452.0 g	1398	90.71	193 15	1.54	17.12	4.27	0.60	44.65	615.36	144.39	141.18	140.64

Table H-4.Average Blast Parameters for the East Wall Gauge.

		Max Peak				DURATIONS (ms)							
	Number of	(kpa)		(dB)		A		B		C		D	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	16	5 39	3.98	167.59	3.72	0.93	0.15	254 64	70.78	115 80	37.02	73.45	41.71
2	17	6 96	1.84	170 58	2.25	1.82	0.65	304 79	71.79	126 56	29.66	105.48	30.30
3	18	10 10	2 21	173.90	1.85	1.66	0.51	276.37	56 92	105.74	19.74	87.83	23.17
4	17	16 40	3.52	178.12	1.78	2.13	0.47	268 88	31.10	99.24	9.15	81.11	15.94
5	19	27 40	6.97	182.55	1.85	1.82	1.02	217.99	27 43	86.84	10.59	73.93	22.16
6	64	37 51	6.90	185 35	1.56	2.55	1.21	214.94	55.98	87.81	29.76	78.14	24.42
7	15	45 36	7 10	187 04	1.31	4.08	0.95	232 12	36.28	82.77	9.30	90.47	19.86

		IMPULSE (kpa*ms)				ENERGY (SEL)					
	Number of	A		Max		Total		A Weighted		P Weighted	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	16	2.08	1.44	50 78	85.10	129 73	5.25	128.79	4.51	128.15	4.42
2	17	5.30	2.42	72 15	145.06	133 54	2.80	131 74	1.92	130.99	1.86
3	18	8 12	3.28	64.44	85 69	135 91	3.02	134 06	2.06	133.20	1.90
4	17	13 80	4.26	118.43	154.10	139 76	1.32	137.57	1.19	136.71	1.37
5	19	21 33	19 35	286.59	277 50	143 76	1.86	140 97	1.53	140.28	1.71
6	64	39.05	21 12	376.38	402 23	146 63	1.29	142 61	1.11	141.93	1.27
7	15	78.95	21 02	692.19	473.38	148 36	1.19	143 82	1.08	143.28	1.30

Table H-5.Average Blast Parameters for the Head Position for the 3-m Distance.

		Max Peak				DURATIONS (ms)							
	Number of	(kpa)		(dB)		A		B		C		D	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	24	9.97	0.77	173.95	0.70	1.40	0.08	22.55	6.67	6.31	0.77	1.01	0.76
2	43	15.60	0.65	177.86	0.36	1.39	0.22	21.07	6.78	6.86	0.89	1.35	1.77
3	34	21.94	0.77	180.82	0.31	1.49	0.05	19.35	6.53	6.34	0.73	3.56	3.43
4	18	33.91	1.22	184.60	0.31	1.48	0.04	17.10	2.17	5.84	0.87	1.22	1.73
5	11	51.08	8.30	188.07	1.31	1.64	0.18	17.40	2.31	5.79	1.27	0.78	0.09
6	376	68.70	2.76	190.73	0.35	1.57	0.32	15.43	1.67	4.29	0.76	0.63	0.05
7	9	95.51	9.70	193.56	0.87	1.40	0.15	17.73	1.73	4.11	1.32	0.60	0.07

		IMPULSE (kpa*ms)				ENERGY (SEL)					
	Number of	A		Max		Total		A Weighted		P Weighted	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	24	5.29	0.34	54.91	65.12	128.87	3.79	123.49	0.99	123.04	1.08
2	43	8.39	1.32	69.77	71.72	130.75	1.62	127.56	0.34	126.92	0.44
3	34	12.87	0.53	74.87	85.40	133.26	1.51	130.58	0.51	130.02	0.65
4	18	19.96	0.90	46.14	42.59	136.26	1.03	134.04	0.47	133.40	0.55
5	11	29.20	1.76	96.76	67.19	139.11	1.02	136.78	0.96	136.33	0.93
6	376	34.14	1.82	221.92	115.10	140.84	0.43	138.81	0.33	138.40	0.36
7	9	43.49	0.93	354.43	140.35	144.24	0.42	141.40	0.40	140.94	0.47

Table H-6.Average Calibration Parameters for East Wall Gauge.

		Max Peak				DURATIONS (ms)							
	Number of	(kpa)		(dB)		A		B		C		D	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	9	3.92	0.50	165.57	1.13	1.28	0.05	388.16	64.53	170.19	23.95	121.15	42.56
2	9	5.63	1.33	168.81	1.64	1.46	0.40	425.21	42.50	163.92	21.22	119.27	31.90
3	7	9.11	0.87	173.15	0.84	1.13	0.17	393.13	20.20	142.58	13.49	70.59	16.08
4	9	16.96	2.04	178.53	1.05	1.52	0.43	278.99	26.89	95.47	13.43	58.78	13.87
5	9	20.30	1.73	180.12	0.93	2.02	0.47	324.24	42.92	115.37	11.24	104.83	29.01
6	29	32.29	2.92	184.15	0.77	2.32	0.82	262.18	22.11	93.72	8.44	98.58	20.34
7	10	36.23	3.69	185.14	0.91	3.53	0.99	263.48	10.62	86.38	9.82	104.19	19.71

		IMPULSE (kpa*ms)				ENERGY (SEL)					
	Number of	A		Max		Total		A Weighted		P Weighted	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	9	1.82	0.13	8.97	8.76	129.00	0.62	129.58	0.52	129.23	0.53
2	9	3.44	0.85	9.50	4.32	132.26	1.34	132.38	1.23	131.90	1.18
3	7	4.94	0.78	9.78	0.56	135.46	0.48	135.72	0.50	135.13	0.50
4	9	9.77	1.23	16.18	1.04	139.87	0.28	138.27	0.23	137.75	0.26
5	9	14.77	4.13	28.17	1.56	142.15	0.29	141.05	0.22	140.54	0.23
6	29	32.08	9.55	67.89	3.75	145.51	0.24	143.44	0.26	143.12	0.26
7	10	43.66	10.31	79.23	4.43	145.94	0.19	143.73	0.29	143.29	0.35

Table H-7.Average Calibration Parameters, Gauge at Head Position, Odd Position (Left Side of Tube) or Left Ear Closest to the Front Wall.

		Max Peak				DURATIONS (ms)							
	Number of	(kpa)		(dB)		A		B		C		D	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	7	2.98	0.54	163.06	1.64	0.28	0.44	347.31	210.79	221.24	143.76	212.38	193.34
2	7	3.88	0.93	165.56	2.05	0.45	0.58	392.90	208.15	220.05	88.87	157.54	115.10
3	7	5.85	0.58	169.30	0.88	1.16	0.37	455.33	43.09	169.51	16.22	126.63	30.33
4	7	8.62	0.50	172.70	0.50	1.38	0.44	396.41	30.45	155.47	9.10	146.38	35.40
5	5	13.63	1.94	176.62	1.21	2.22	0.39	385.08	22.30	135.03	19.96	150.00	40.72
6	8	23.41	3.45	181.31	1.24	2.98	1.84	271.70	103.97	104.39	13.74	105.19	59.37
7	11	28.21	5.35	182.87	1.61	3.41	2.18	238.68	111.53	88.61	17.45	96.11	60.60

		IMPULSE (kpa*ms)				ENERGY (SEL)					
	Number of	A		Max		Total		A Weighted		P Weighted	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	7	0.24	0.36	3.54	3.55	126.53	0.72	126.74	0.66	126.85	0.63
2	7	0.68	0.94	4.26	0.74	129.16	0.86	129.24	0.80	129.25	0.79
3	7	2.65	0.58	9.18	4.71	132.61	0.41	132.56	0.42	132.68	0.40
4	7	4.34	0.85	12.83	0.87	135.76	0.35	135.20	0.29	135.35	0.31
5	5	11.43	2.91	23.40	1.61	139.05	0.24	137.80	0.20	137.94	0.30
6	8	25.99	16.12	55.85	5.35	142.95	0.35	139.99	0.32	140.09	0.25
7	11	28.14	17.86	71.49	6.13	143.28	0.35	140.51	0.28	140.71	0.25

Table H-8.Average Calibration Parameters, Gauge at Head Position, Even Position, Right Side at Tube or Right Ear Closest to Front Wall.

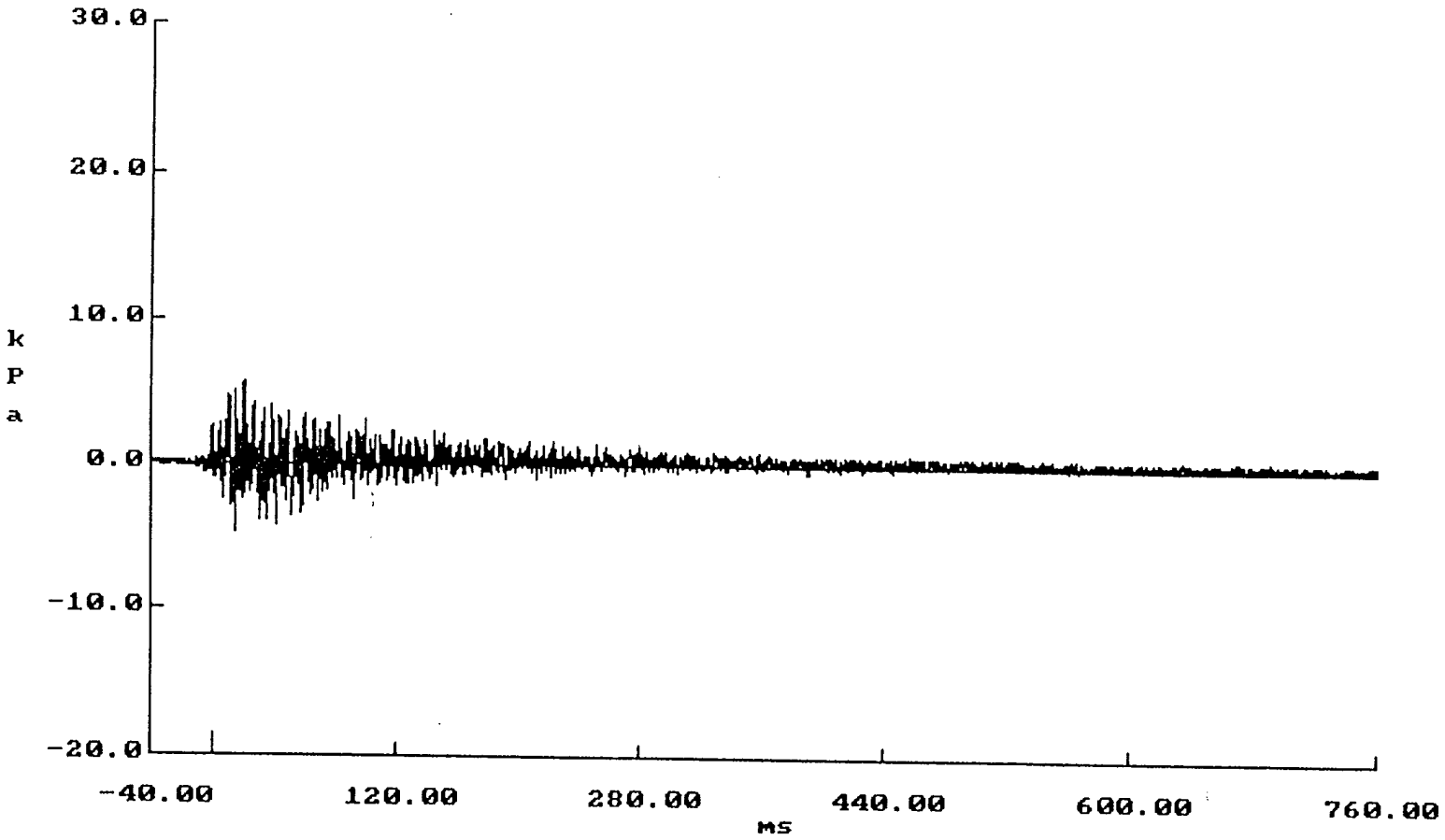
		Max Peak				DURATIONS (ms)							
	Number of	(kpa)		(dB)		A		B		C		D	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	4	3.27	0.37	164.25	0.96	0.45	0.51	361.08	229.09	235.35	124.21	110.00	79.91
2	6	4.86	0.59	167.67	1.10	0.51	0.54	327.47	144.25	181.20	46.39	93.37	68.83
3	7	6.16	0.58	169.76	0.77	1.00	0.45	396.44	118.93	157.17	17.87	126.96	54.13
4	7	8.23	0.73	172.28	0.76	1.29	0.44	391.39	65.63	165.56	16.26	153.88	27.99
5	6	13.75	0.47	176.76	0.80	1.60	0.95	331.74	77.20	126.65	8.76	116.67	52.73
6	6	32.81	6.53	184.18	1.69	3.26	1.87	235.93	97.14	74.84	17.34	73.58	38.42
7	9	29.25	9.06	183.05	2.13	3.01	1.67	272.17	91.48	87.91	21.67	101.01	45.60

		IMPULSE (kpa*ms)				ENERGY (SEL)					
	Number of	A		Max		Total		A Weighted		P Weighted	
Intensity	Shots	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev	Average	Std Dev
1	4	0.56	0.62	53.35	23.30	127.22	0.59	127.31	0.78	127.29	0.83
2	6	1.06	1.14	47.34	30.06	130.11	1.28	129.98	1.18	130.02	1.15
3	7	2.77	1.24	52.50	26.49	132.95	0.46	132.76	0.49	132.91	0.48
4	7	5.07	1.01	40.48	35.97	135.76	0.40	135.37	0.34	135.61	0.34
5	6	8.68	5.87	30.60	8.77	139.19	0.22	138.25	0.21	138.51	0.18
6	6	32.28	17.24	64.29	6.73	143.50	0.58	140.49	0.27	140.58	0.26
7	9	30.50	15.21	77.34	3.79	143.54	0.22	140.79	0.27	140.90	0.29

Table H-9. Parameters for the Waveforms of Figures H-16 and 17.

Gage Location	Intensity	Charge Weight	Test ID	Max Peak (kpa)	Max Peak (dB)	DURATIONS A (ms)	DURATIONS B (ms)	DURATIONS C (ms)	DURATIONS D (ms)	IMPULSE A (kpa*ms)	IMPULSE Max (kpa*ms)	ENERGY (SEL) Total (SEL)	ENERGY (SEL) A Weighted (SEL)	ENERGY (SEL) P Weighted (SEL)
EAST WALL	6	1.75 lb	S03C25	31.61	184.00	3.12	274.90	93.95	90.34	38.67	67.56	145.47	143.25	142.90
TROOP ODD	6	1.75 lb	S03C25	22.65	181.10	4.64	334.94	112.86	148.30	38.99	55.16	142.21	139.43	139.78
TROOP EVEN	6	1.75 lb	S02C25	28.70	183.16	2.56	261.59	78.74	73.18	18.72	54.75	142.38	139.96	140.18

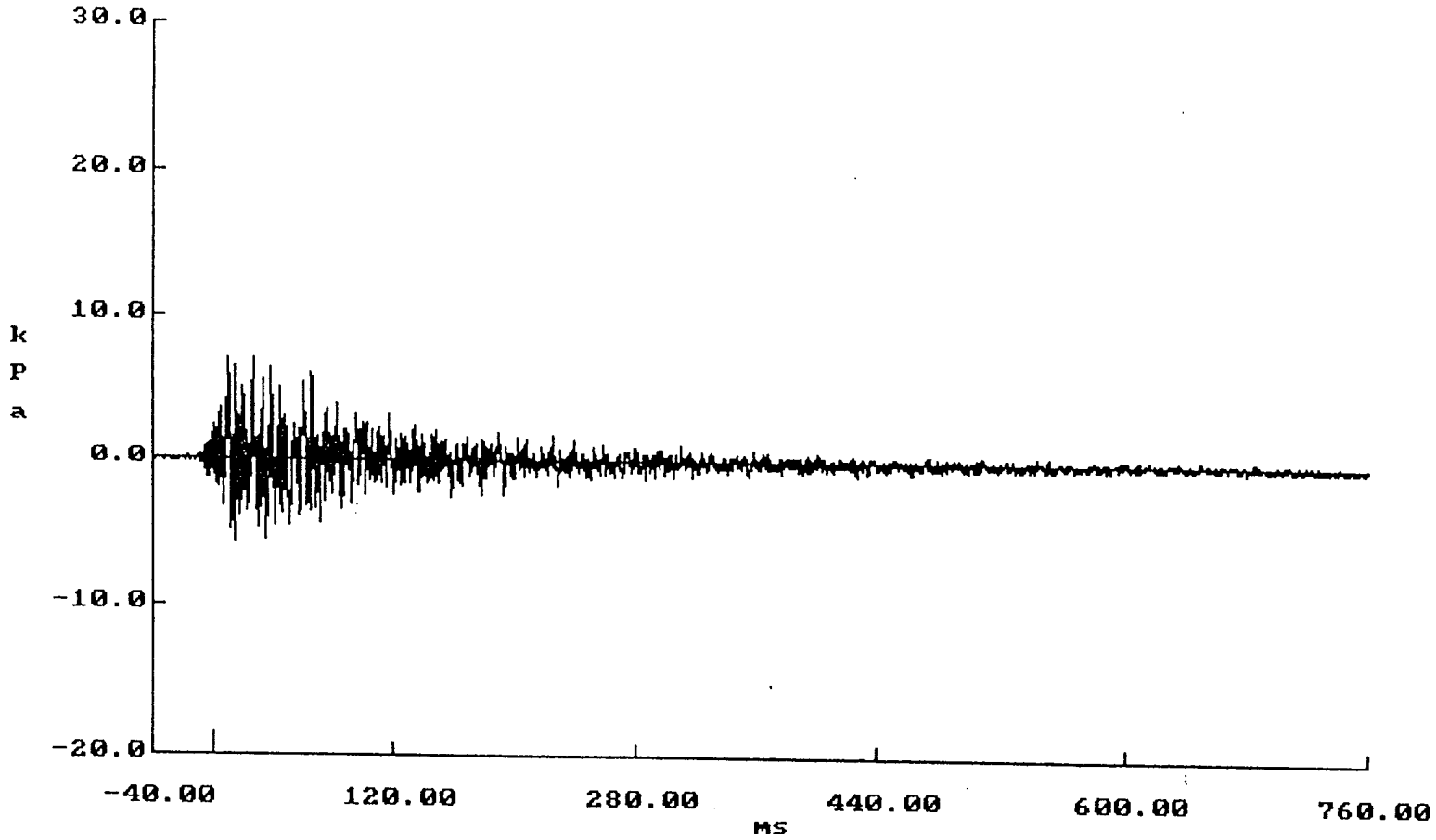
Figure H-1.Typical Waveforms, East Wall Gauge, Level 1, Firing from a Bunker Simulation.



Positive peak = 5.66 kPa at 20.51 ms
Negative peak = -4.69 kPa at 14.328 ms
A Duration = 0.86 ms at 20.136 ms to 20.992 ms
B Duration = 289.66 ms
Incident peak = 2.66 kPa
Incident peak is at 0.024 ms
A Impulse = 2.45 kPa*ms
Trigger Time = 2.351960 sec

1101-6.4g
east wall 03
Wed Nov 9 10:36:18 1994

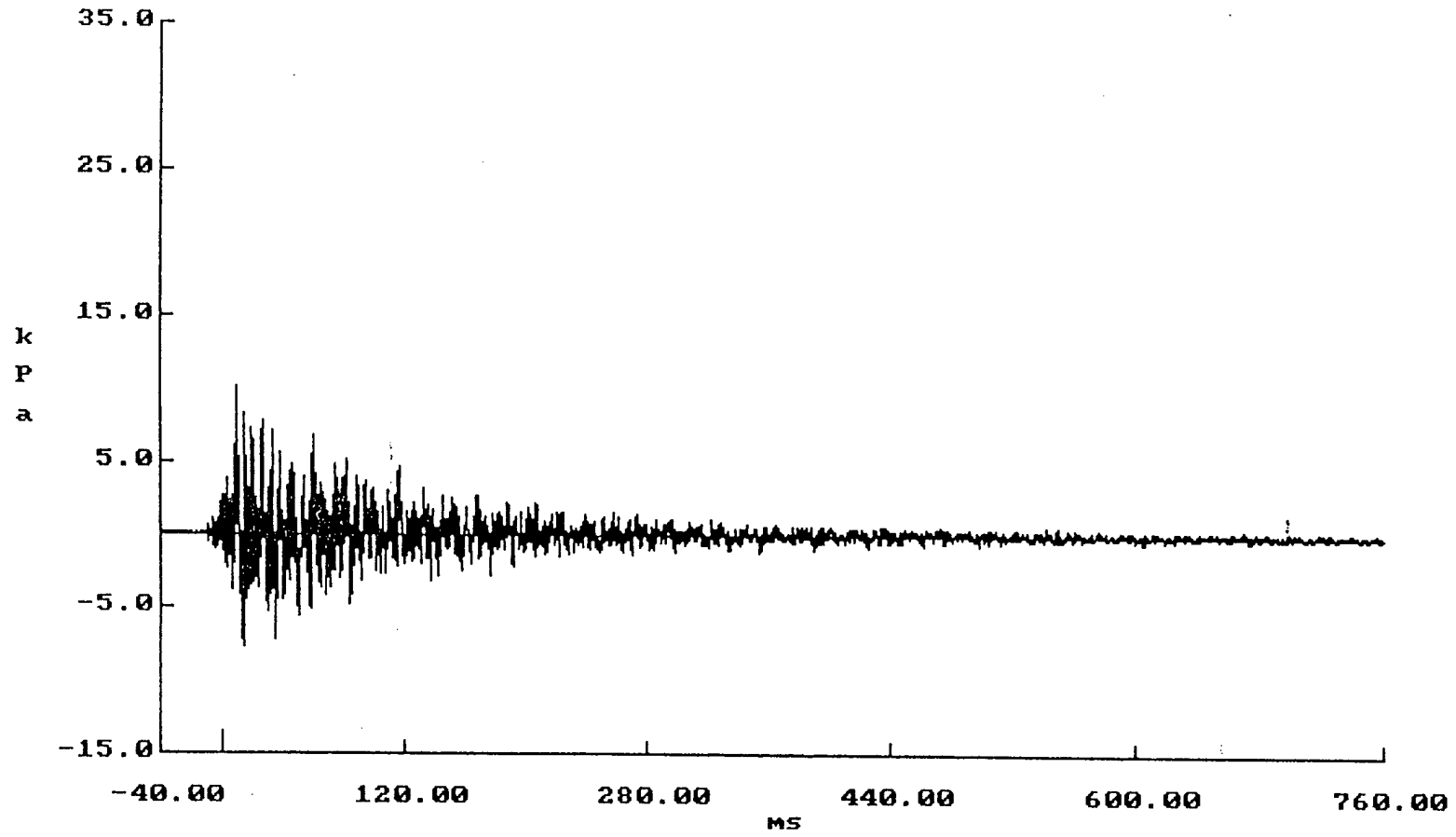
Figure H-2.Typical Waveforms, East Wall Gauge, Level 2, Firing from a Bunker Simulation.



Positive peak = 6.99 kPa at 27.02 ms
Negative peak = -5.71 kPa at 14.304 ms
A Duration = 2.42 ms at 25.856 ms to 28.272 ms
B Duration = 327.97 ms
Incident peak = 2.36 kPa
Incident peak is at 0.008 ms
A Impulse = 6.42 kPa*ms
Trigger Time = 2.765368 sec

1104-12.5g
east wall 03
Thu Nov 10 09:27:12 1994

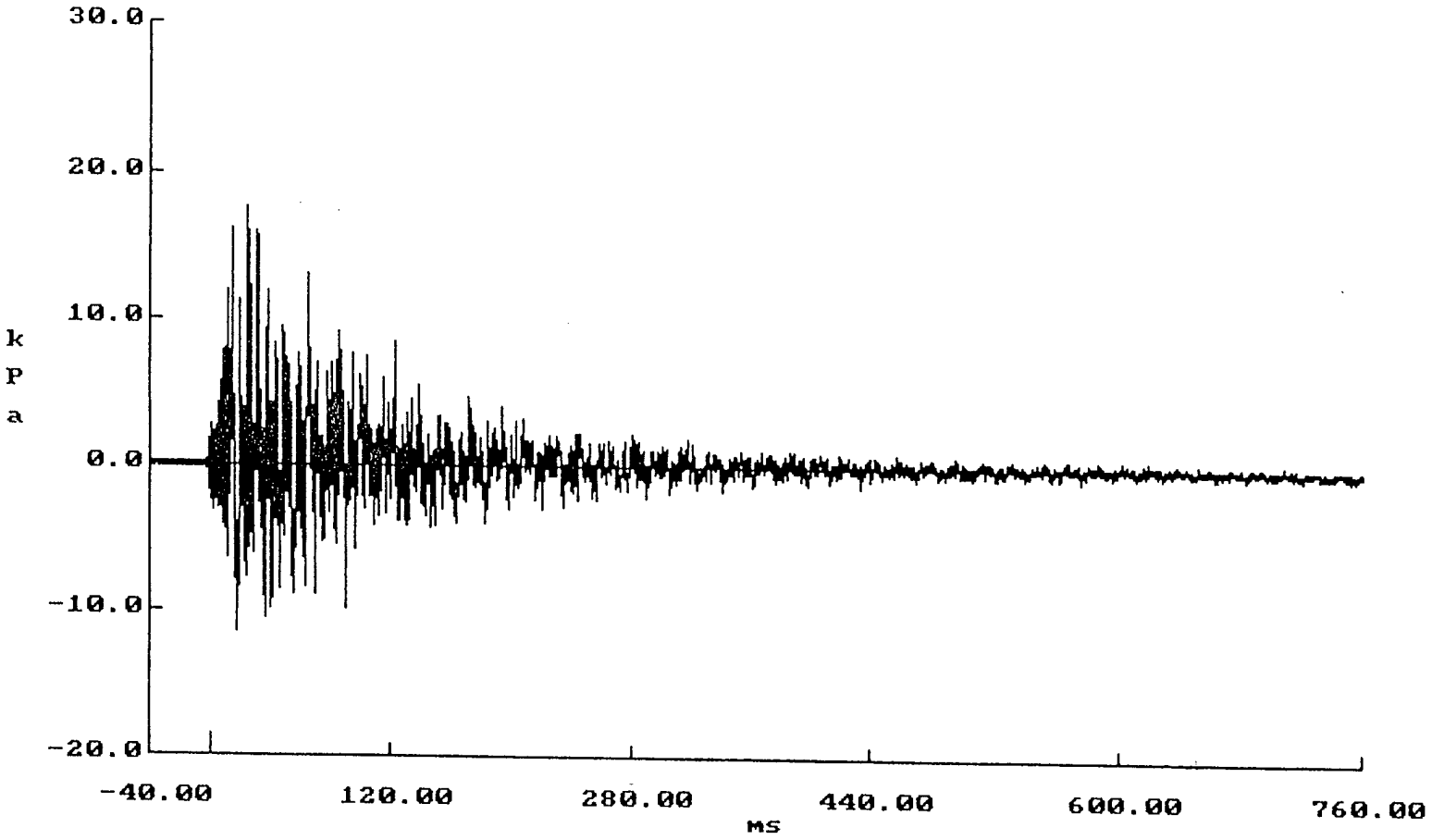
Figure H-3.Typical Waveform of East Wall Gauge, Level 3, Firing from a Bunker Simulation.



Positive peak = 10.06 kPa at 10.13 ms
Negative peak = -7.78 kPa at 14.208 ms
A Duration = 2.06 ms at 9.424 ms to 11.488 ms
B Duration = 279.29 ms
Incident peak = 3.93 kPa
Incident peak is at 3.872 ms
A Impulse = 9.02 kPa*ms
Trigger Time = 2.131272 sec

1105-23g
east wall 03
Fri Nov 11 08:55:58 1994

Figure H-4.Typical Waveforms of East Wall Gauge, Level 4, Firing from a Bunker Simulation.



Positive peak = 17.78 kPa at 24.98 ms
Negative peak = -11.48 kPa at 18.552 ms
A Duration = 1.07 ms at 24.600 ms to 25.672 ms
B Duration = 224.65 ms
Incident peak = 5.79 kPa
Incident peak is at 7.584 ms
A Impulse = 10.09 kPa*ms
Trigger Time = 2.416816 sec

1146-50g
east wall 03
Mon Jan 23 12:51:02 1995

Figure H-5.Typical Waveforms of East Wall Gauge, Level 5, Firing from a Bunker Simulation.

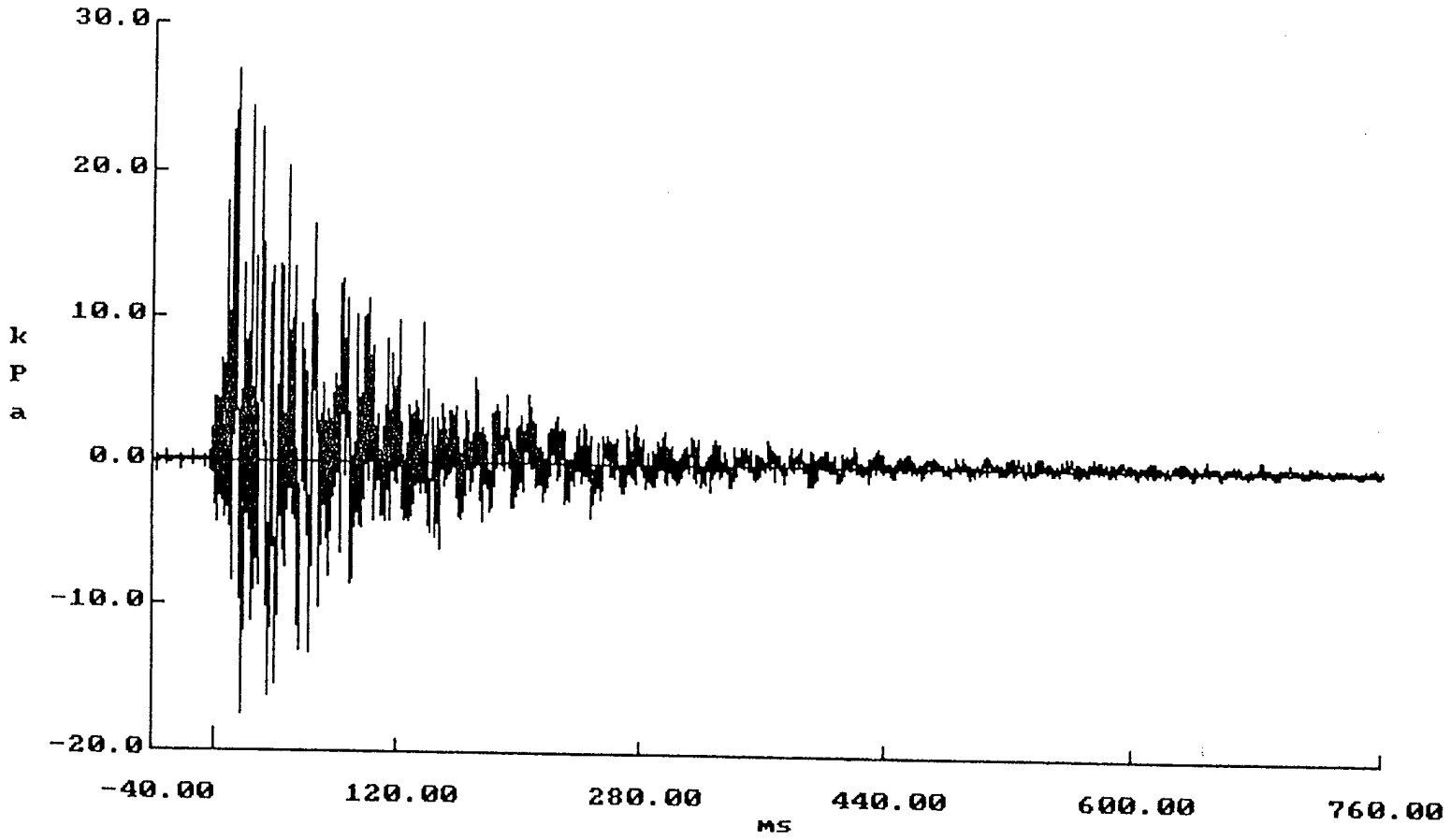
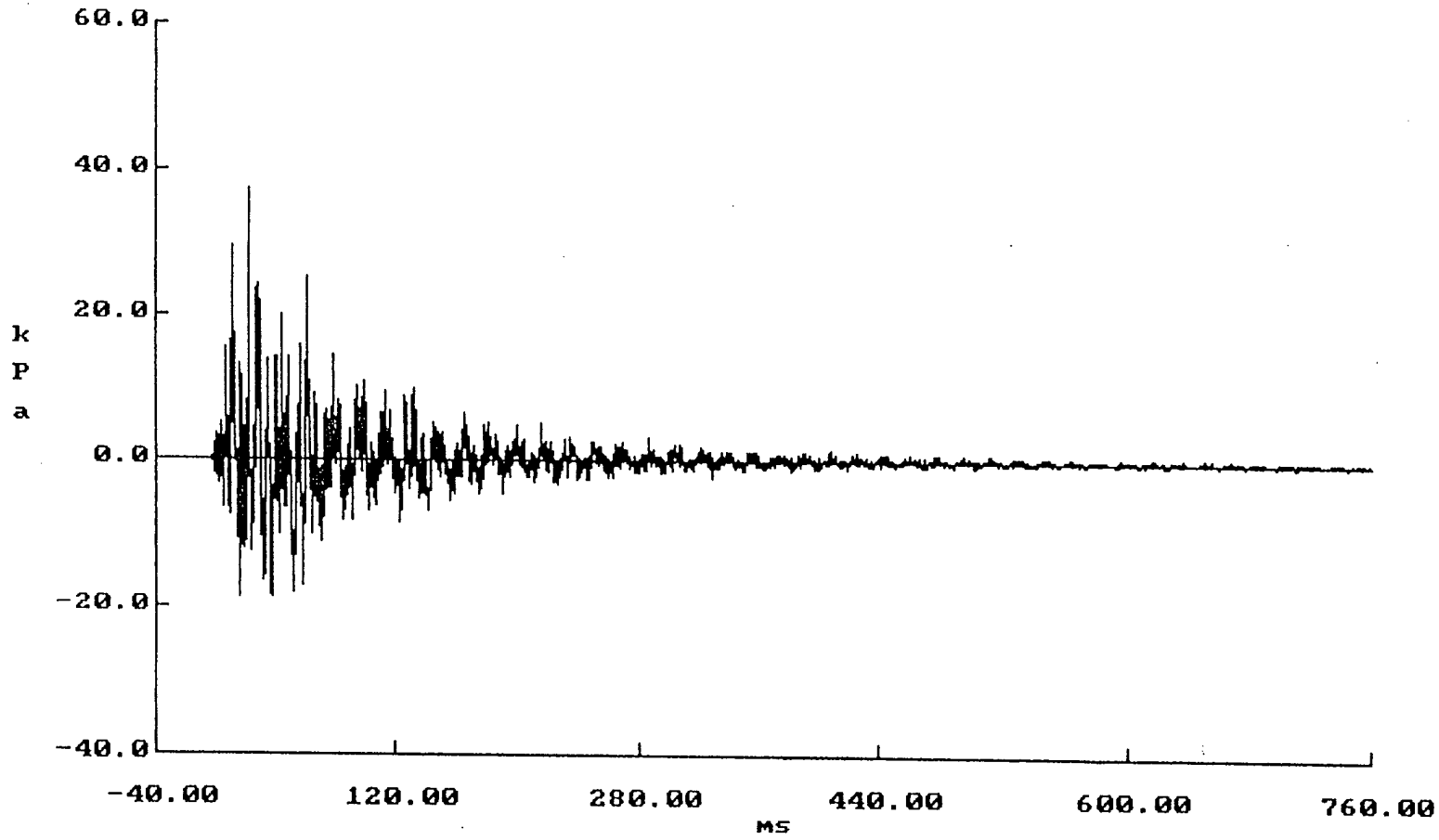


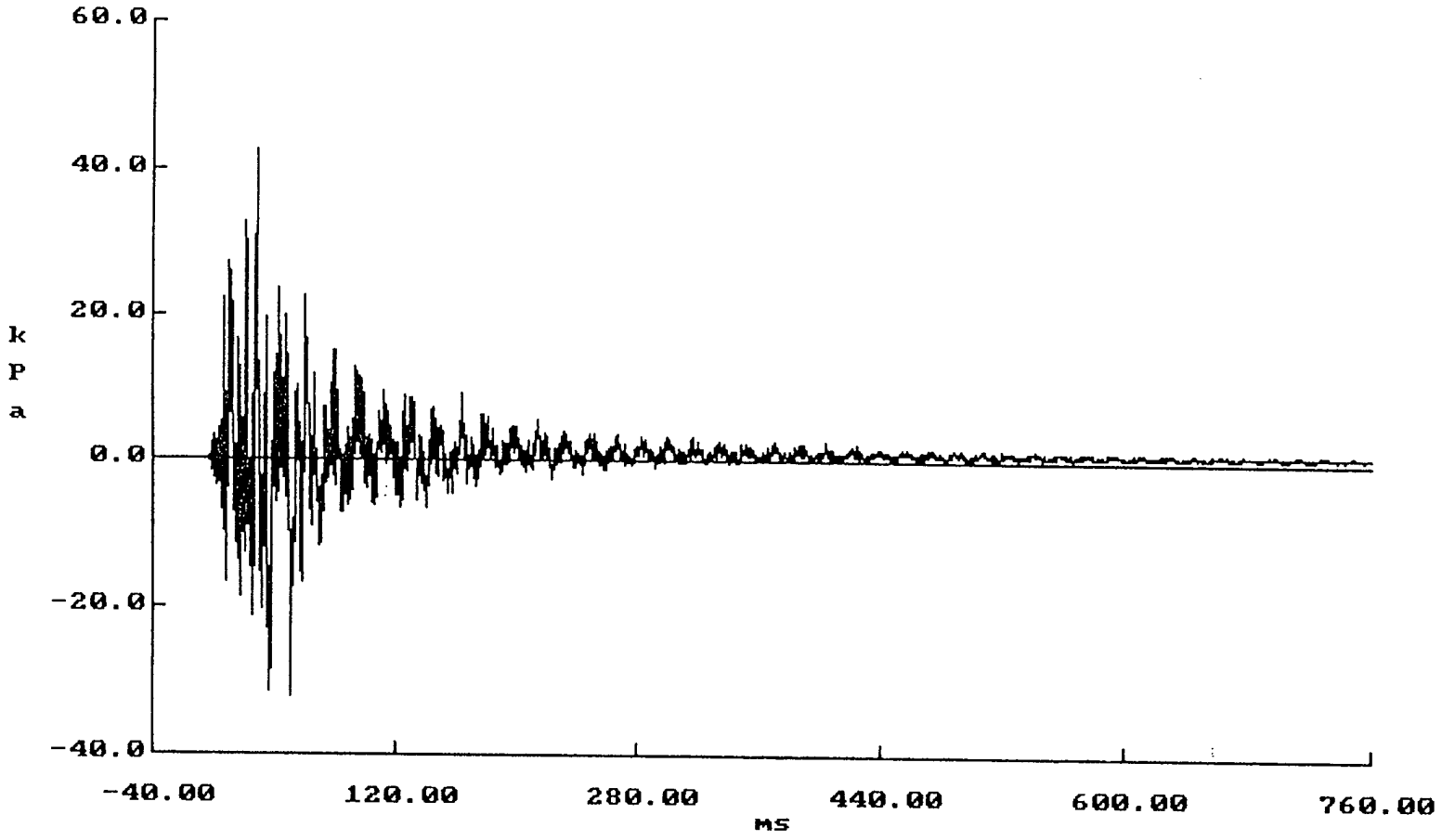
Figure H-6.Typical Waveforms of East Wall Gauge, Level 6, Firing from a Bunker Simulation.



Positive peak = 37.49 kPa at 22.34 ms
Negative peak = -18.82 kPa at 38.456 ms
A Duration = 1.37 ms at 22.080 ms to 23.448 ms
B Duration = 163.06 ms
Incident peak = 13.80 kPa
Incident peak is at 6.896 ms
A Impulse = 19.85 kPa*ms
Trigger Time = 2.081336 sec

1095-L6-203g
east wall 03
Thu Sep 29 09:44:12 1994

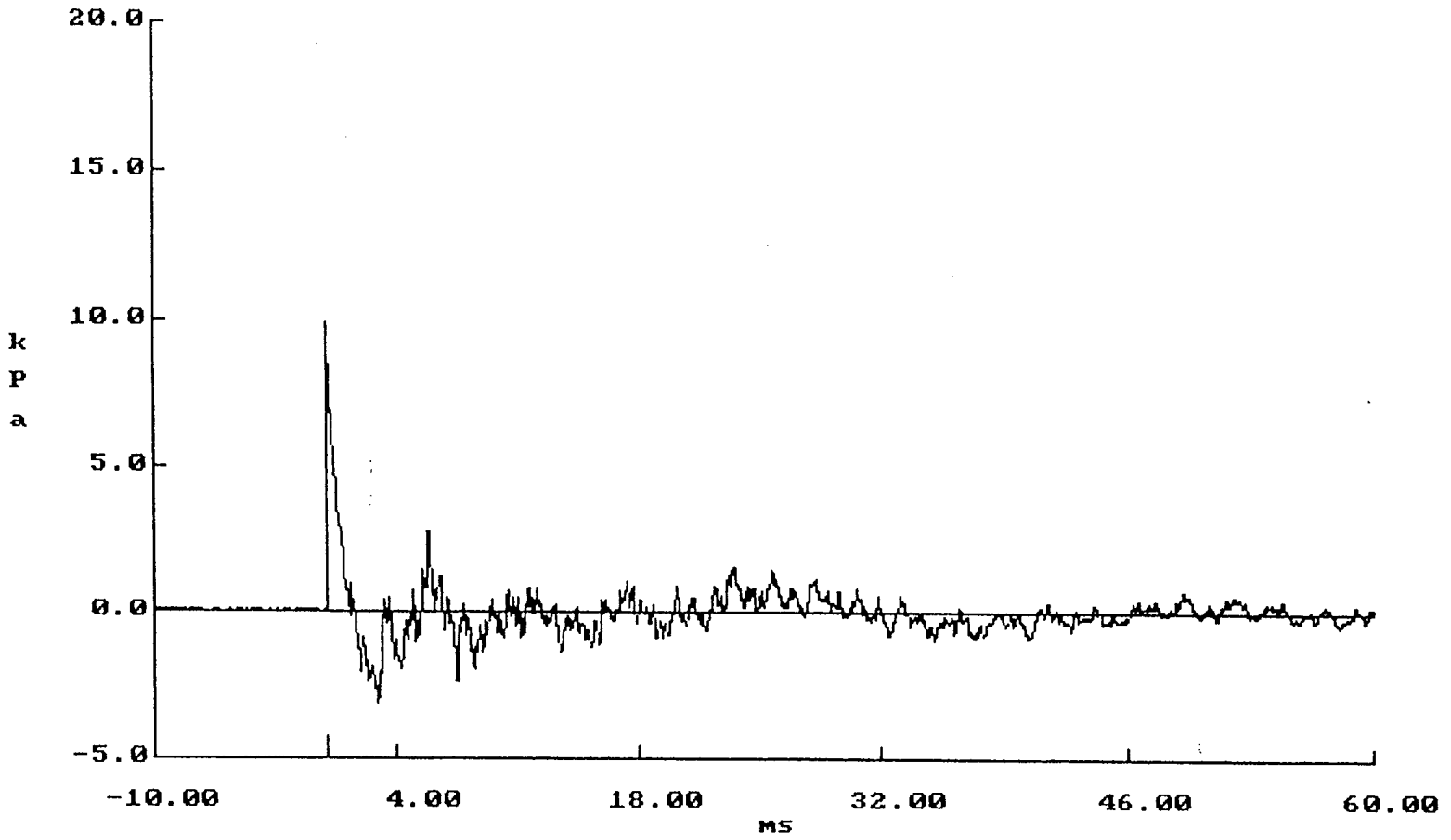
Figure H-7.Typical Waveform of East Wall Gauge, Level 7, Firing from a Bunker Simulation.



Positive peak = 42.66 kPa at 28.30 ms
Negative peak = -32.27 kPa at 51.584 ms
A Duration = 3.08 ms at 27.144 ms to 30.224 ms
B Duration = 209.41 ms
Incident peak = 21.35 kPa
Incident peak is at 6.704 ms
A Impulse = 48.74 kPa*ms
Trigger Time = 1.983984 sec

1092-L7 — 245g
east wall 03
Wed Sep 28 12:18:08 1994

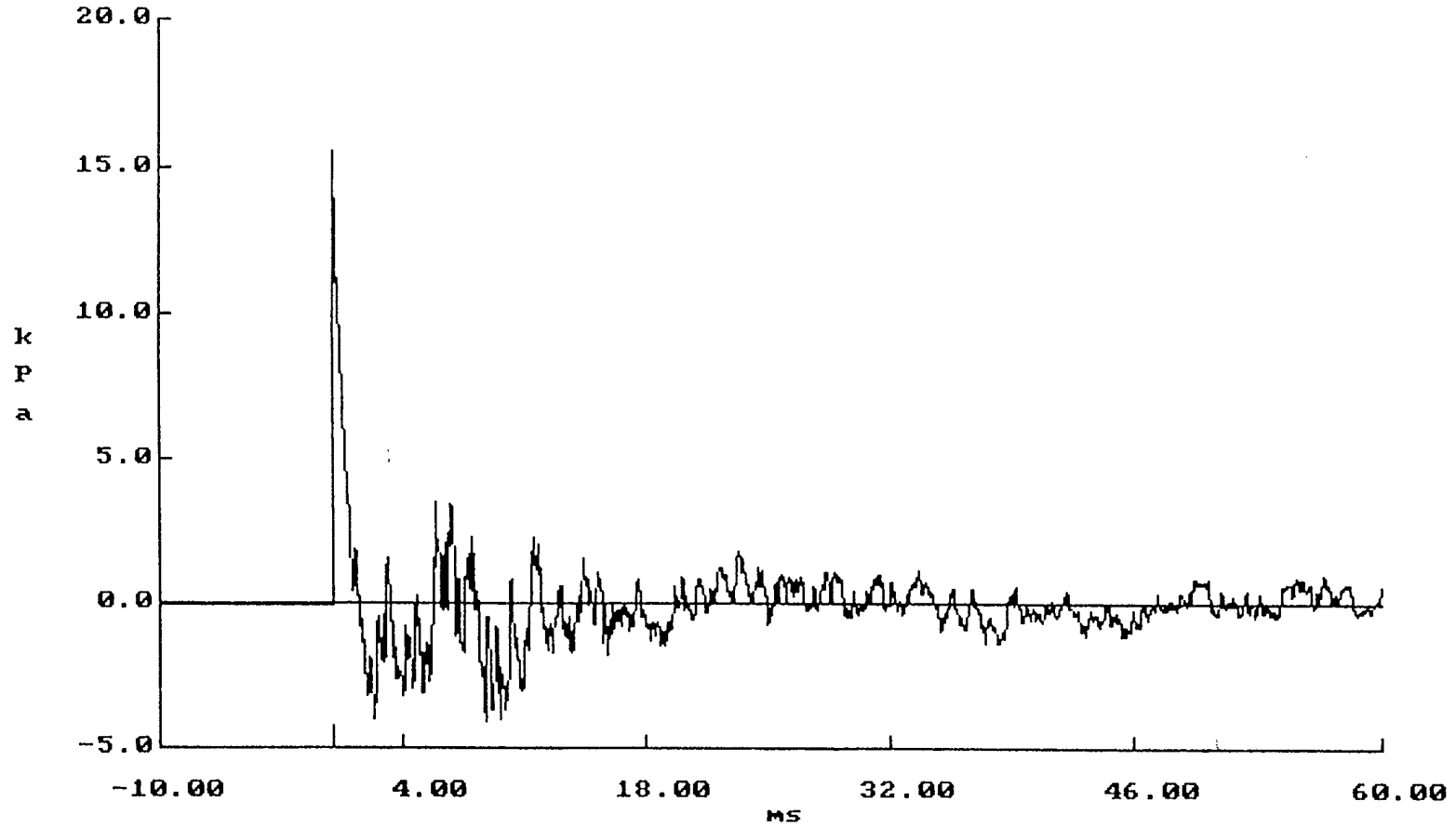
Figure H-8.Typical Waveforms of the 3-m Distance, Level 1.



Positive peak = 9.92 kPa at 0.02 ms
Negative peak = -3.08 kPa at 2.952 ms
A Duration = 1.36 ms at -0.024 ms to 1.336 ms
B Duration = 28.26 ms
Incident peak = 9.92 kPa
Incident peak is at 0.016 ms
A Impulse = 5.14 kPa*ms
Trigger Time = 2.901912 sec

1357-45.3g
PCB EAST 02
Wed Sep 27 13:10:42 1995

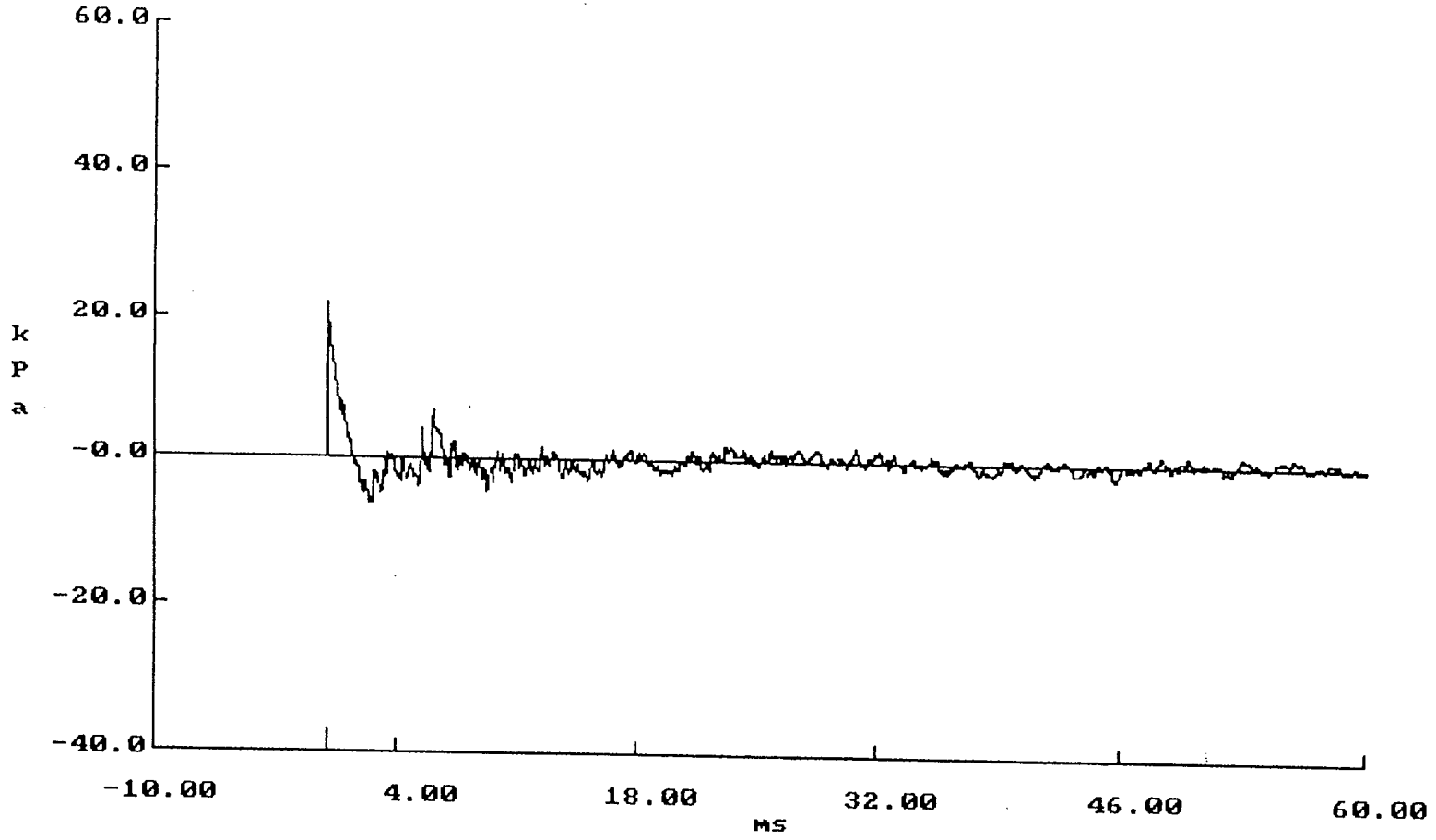
Figure H-9.Typical Waveforms of the 3-m Distance, Level 2.



Positive peak = 15.57 kPa at 0.02 ms
Negative peak = -4.09 kPa at 8.768 ms
A Duration = 1.50 ms at -0.024 ms to 1.472 ms
B Duration = 15.80 ms
Incident peak = 15.57 kPa
Incident peak is at 0.024 ms
A Impulse = 8.44 kPa*ms
Trigger Time = 2.455240 sec

1363-95.3g
PCB EAST 02
Tue Oct 3 10:42:48 1995

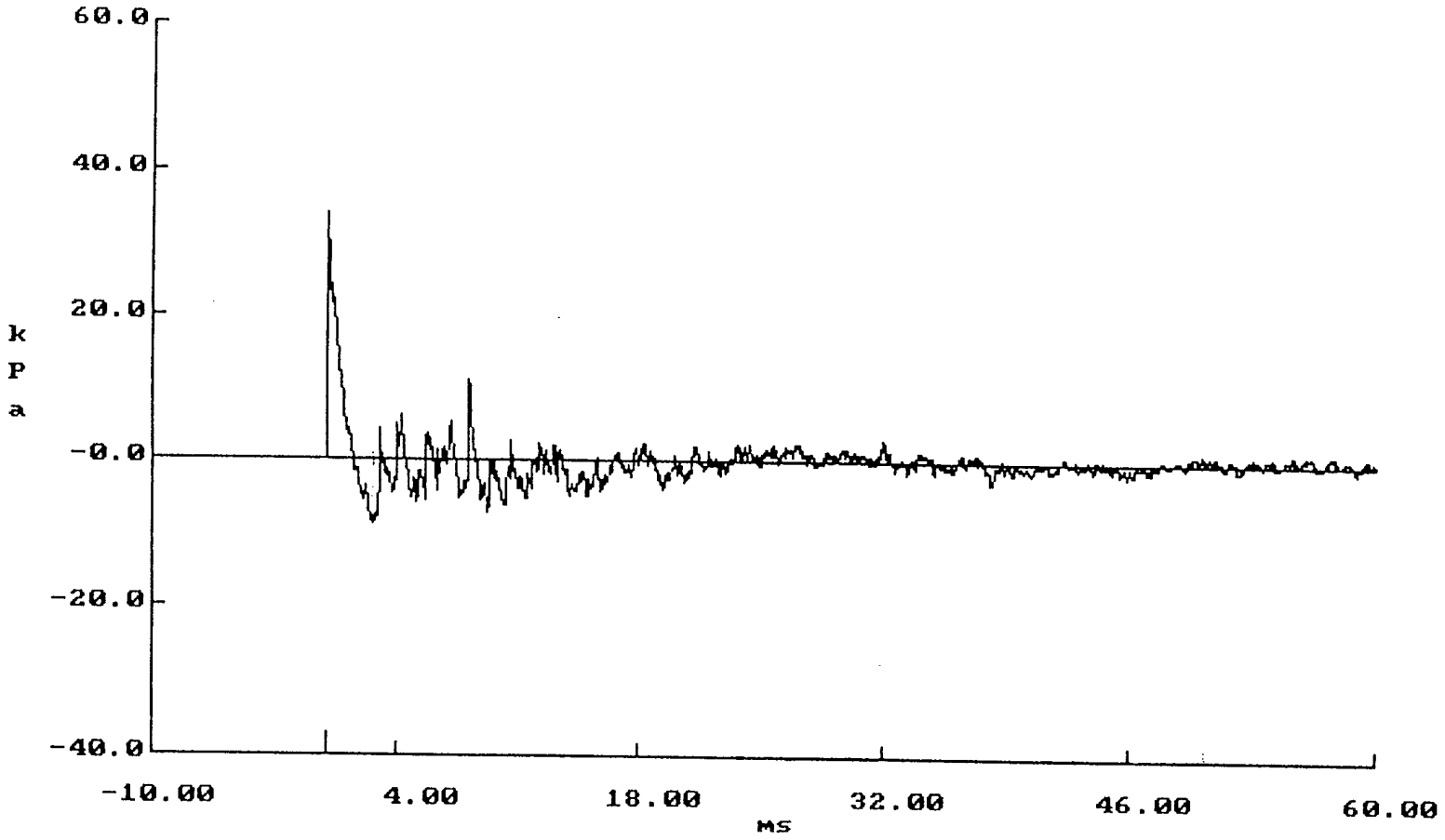
Figure H-10.Typical Waveforms of the 3-m Distance, Level 3.



Positive peak = 22.00 kPa at 0.02 ms
Negative peak = -6.27 kPa at 2.616 ms
A Duration = 1.51 ms at -0.064 ms to 1.448 ms
B Duration = 15.24 ms
Incident peak = 22.00 kPa
Incident peak is at 0.016 ms
A Impulse = 12.85 kPa*ms
Trigger Time = 3.000584 sec

1366-181g
PCB EAST 02
Wed Oct 4 11:51:36 1995

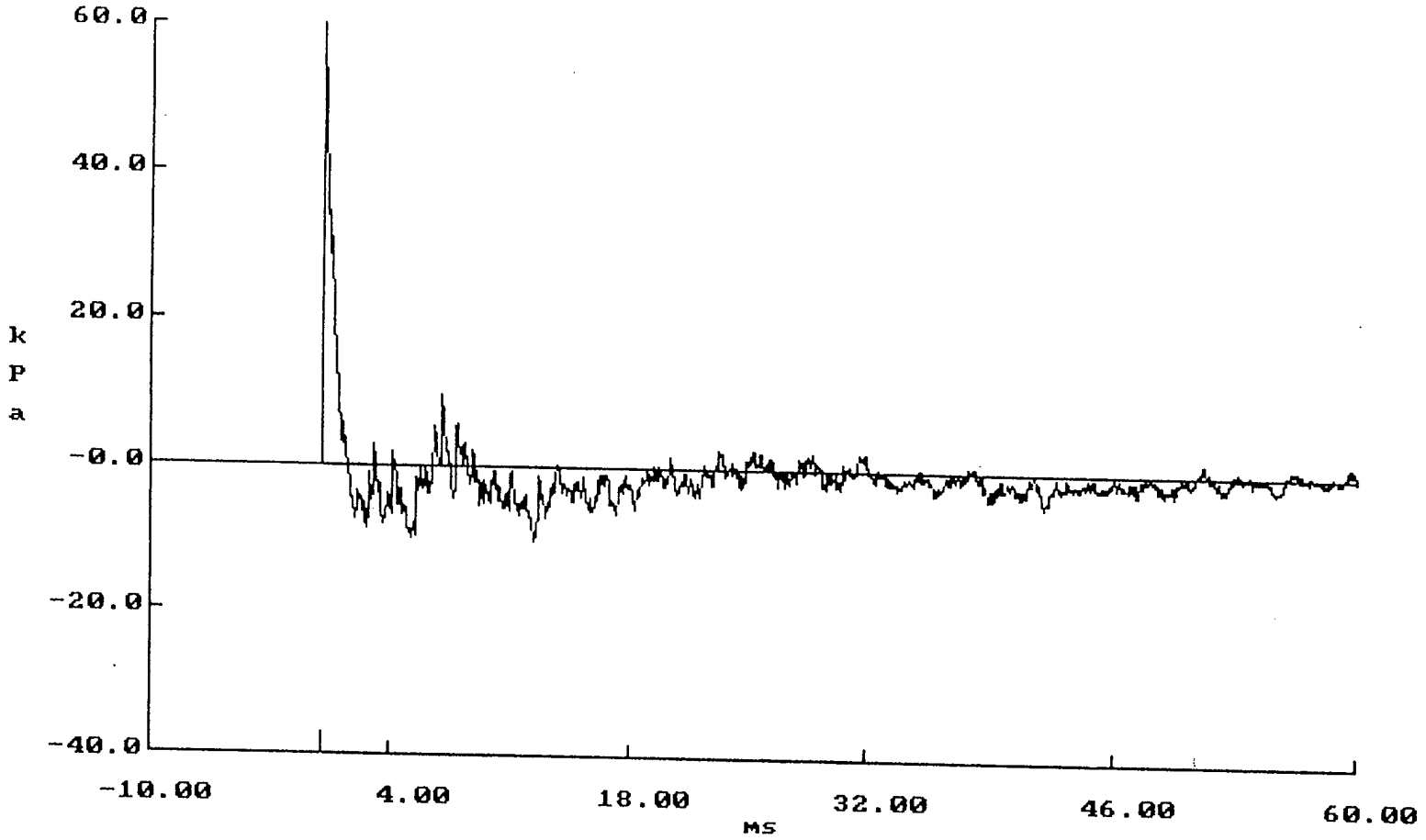
Figure H-11.Typical Waveforms of the 3-m Distance, Level 4.



Positive peak = 34.04 kPa at 0.02 ms
Negative peak = -8.89 kPa at 2.624 ms
A Duration = 1.50 ms at -0.032 ms to 1.472 ms
B Duration = 19.50 ms
Incident peak = 34.04 kPa
Incident peak is at 0.024 ms
A Impulse = 20.41 kPa*ms
Trigger Time = 3.623216 sec

1371-367g
PCB EAST 02
Fri Oct 6 13:22:16 1995

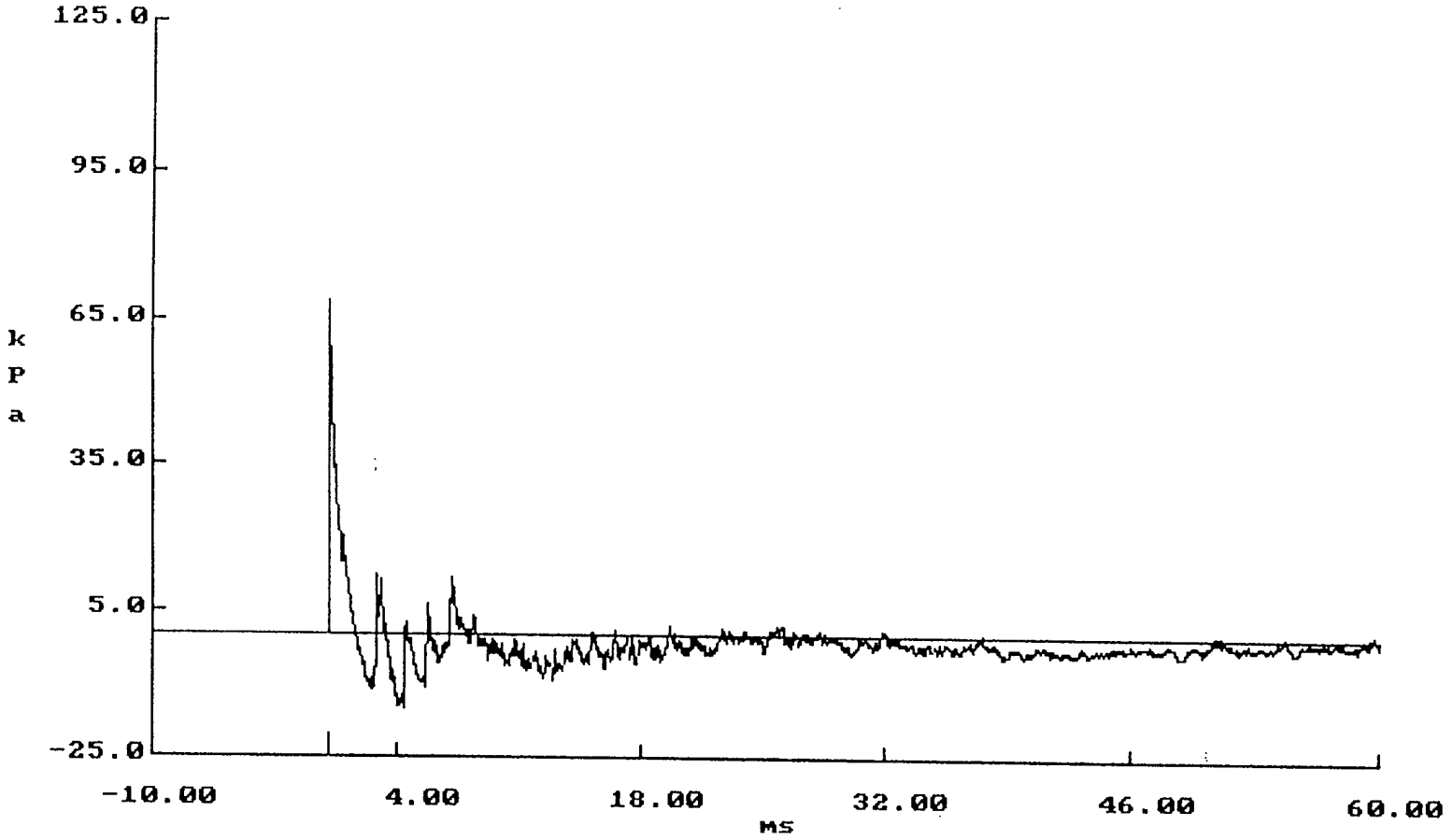
Figure H-12.Typical Waveforms of the 3-m Distance, Level 5.



Positive peak = 60.32 kPa at 0.02 ms
Negative peak = -10.36 kPa at 12.408 ms
A Duration = 1.51 ms at -0.040 ms to 1.472 ms
B Duration = 17.18 ms
Incident peak = 60.32 kPa
Incident peak is at 0.024 ms
A Impulse = 32.11 kPa*ms
Trigger Time = 3.015016 sec

1386-680g
PCB EAST 02
Fri Oct 20 13:04:58 1995

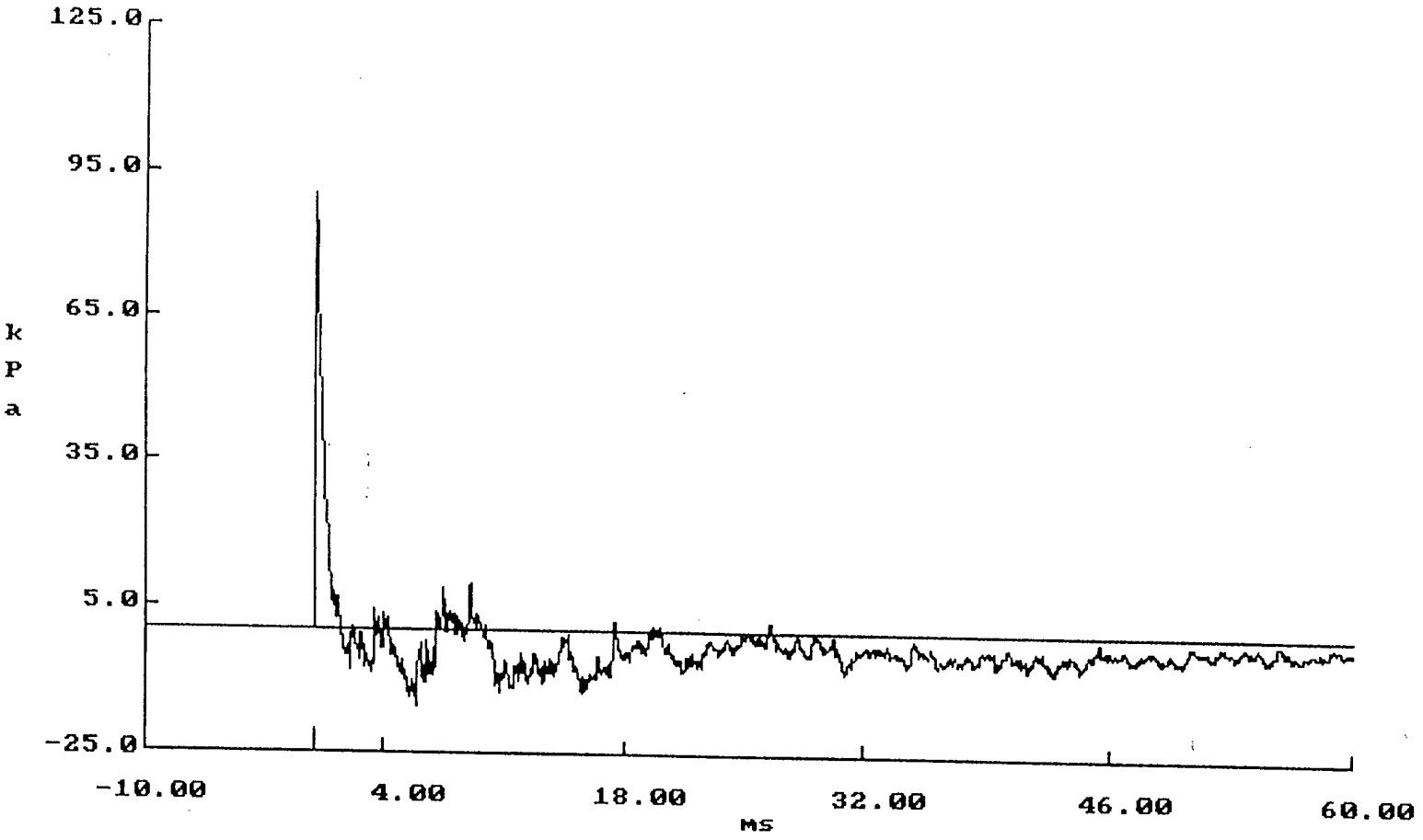
Figure H-13.Typical Waveform of the 3-m Distance, Level 6.



Positive peak = 69.01 kPa at 0.02 ms
Negative peak = -14.93 kPa at 4.392 ms
A Duration = 1.61 ms at -0.048 ms to 1.560 ms
B Duration = 13.52 ms
Incident peak = 69.01 kPa
Incident peak is at 0.024 ms
A Impulse = 34.19 kPa*ms
Trigger Time = 3.132552 sec

1381-794g
PCB EAST 02
Fri Oct 13 11:32:00 1995

Figure H-14.Typical Waveform of the 3-m Distance, Level 7.



Positive peak = 90.71 kPa at 0.02 ms
Negative peak = -15.53 kPa at 5.936 ms
A Duration = 1.60 ms at -0.056 ms to 1.544 ms
B Duration = 17.12 ms
Incident peak = 90.71 kPa
Incident peak is at 0.024 ms
A Impulse = 44.70 kPa*ms
Trigger Time = 3.197528 sec

S06

1398-1452g
PCB EAST 02
Wed Oct 25 13:57:44 1995

Figure H-15.Regression of Maximum Peak Level vs. Exposure Step for Calibration Shots.

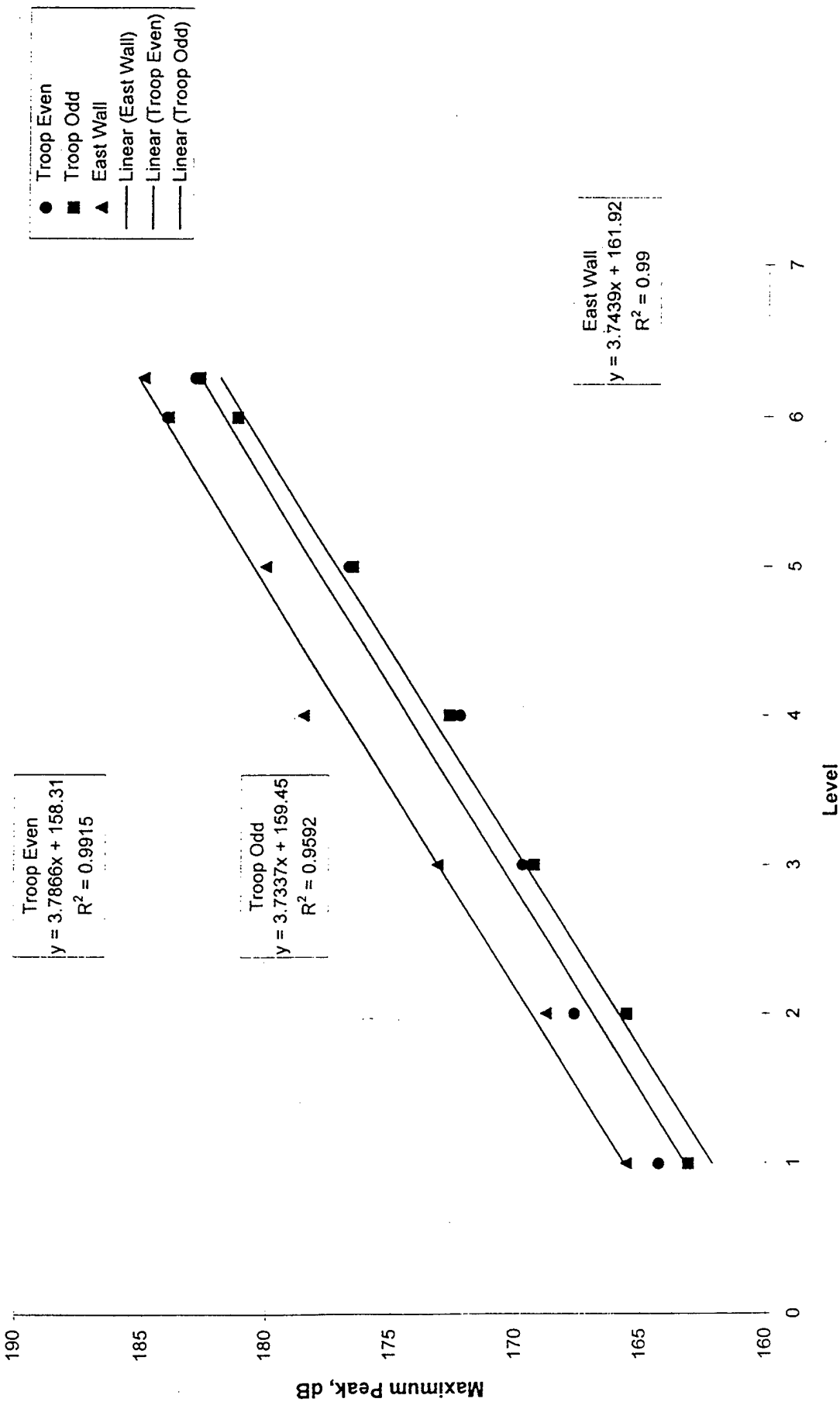
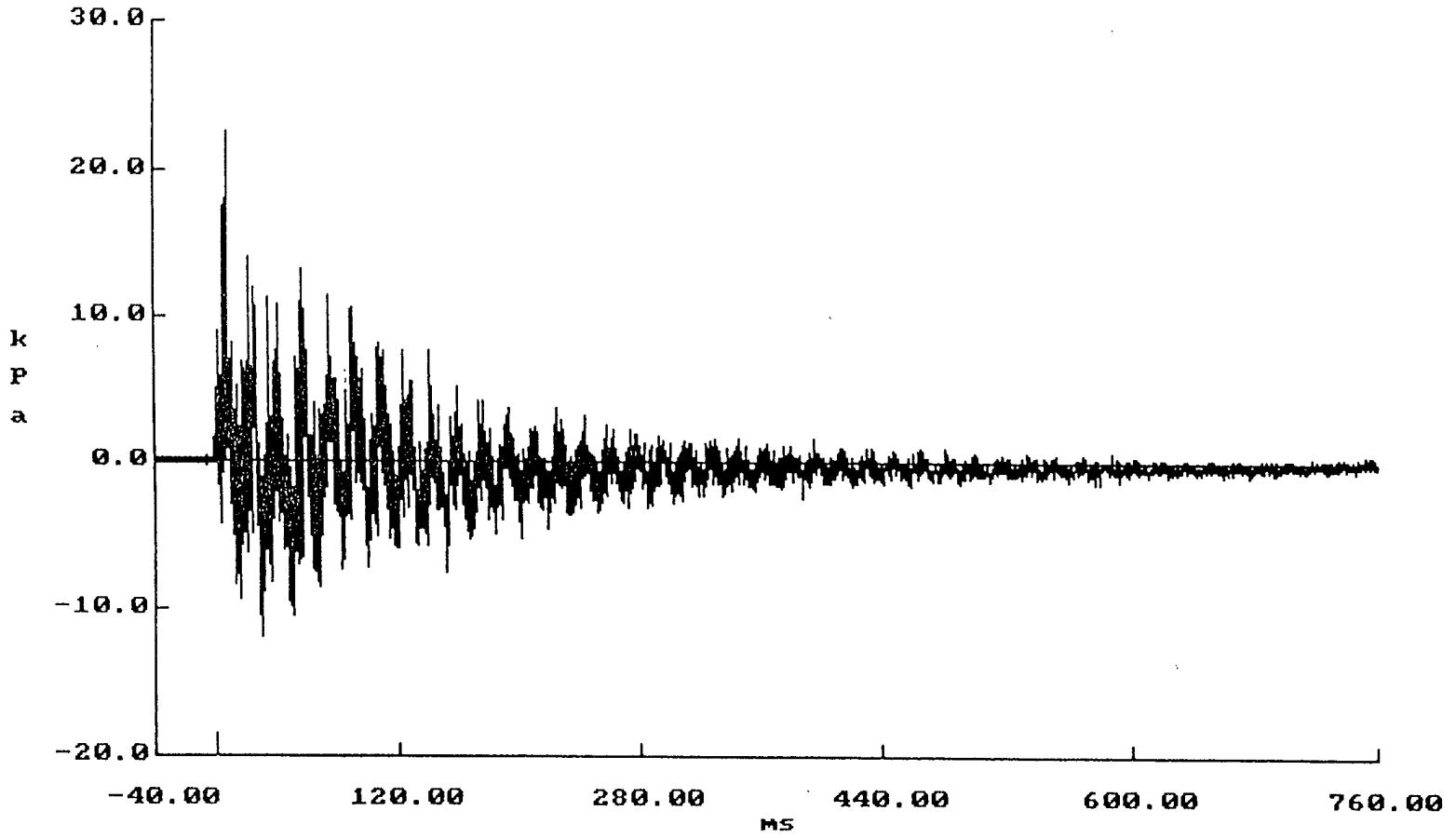


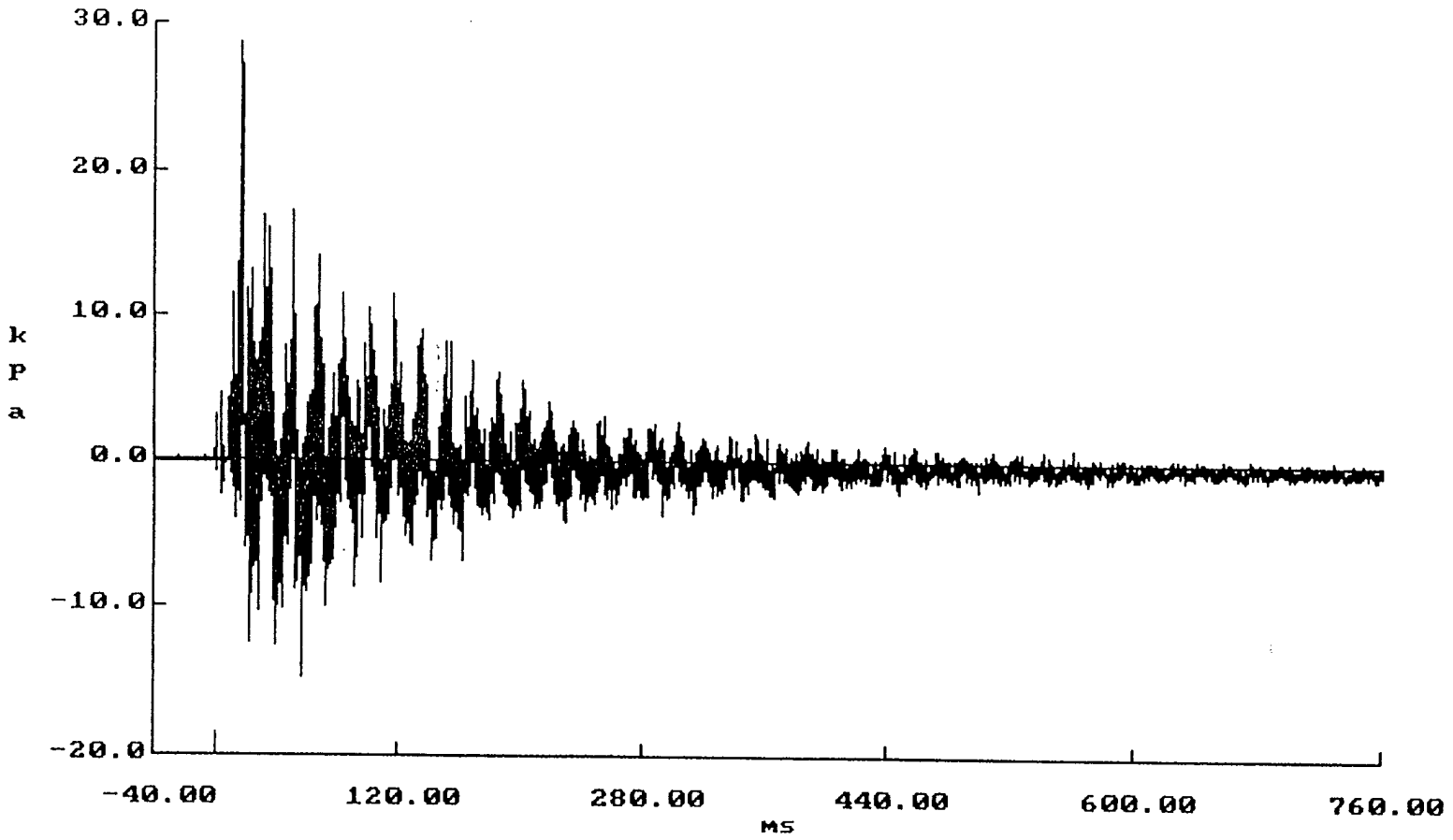
Figure H-16.Typical Waveform at Head Position, Odd Position, Level 6, Firing from a Bunker Simulation.



Positive peak = 22.65 kPa at 8.81 ms
Negative peak = -11.95 kPa at 30.592 ms
A Duration = 4.64 ms at 5.000 ms to 9.640 ms
B Duration = 334.94 ms
Incident peak = 9.04 kPa
Incident peak is at 3.008 ms
A Impulse = 38.99 kPa*ms
Trigger Time = 3.042056 sec

CALIB
Troop Odd
Tue Jul 11 14:16:20 1995

Figure H-17.Typical Waveform at Head Postion, Even Postiion, Level 6, Firing from a Bunker Simulation.



Positive peak = 28.70 kPa at 15.90 ms
Negative peak = -14.70 kPa at 57.768 ms
A Duration = 2.56 ms at 14.256 ms to 16.816 ms
B Duration = 261.59 ms
Incident peak = 9.27 kPa
Incident peak is at 11.488 ms
A Impulse = 18.72 kPa*ms
Trigger Time = 2.925184 sec

CALIB
Troop Even
Tue Jul 11 14:10:12 1995

APPENDIX J

PERFORMANCE ASSESSMENT BATTERY TEST SCORE SUMMARIES

Table J-1

Performance Assessment Battery Test Scores
Firing from a Bunker Simulator Study

Subject No.	Pre/ Post	Level									
		1	2	3	4	5	6	7	6/2	6/3	Total
1012	Pre	396	449	428	397	382	425	405	437	356	3675
	Post	360	326	377	390	383	420	427	436	388	3507
1013	Pre	289	ND	ND	263	300	325	256	385	294	2112
	Post	338	371	329	266	376	399	321	316	314	3030
1015	Pre	486	438	423	481	438	397	388	484	506	4041
	Post	467	468	489	408	506	499	446	396	506	4185
1016	Pre	324	259	288	256	307	265	ND	ND	ND	1699
	Post	283	338	276	265	388	ND	ND	285	ND	1835
1022	Pre	518	447	506	496	515	527	475	520	477	4481
	Post	504	509	436	375	505	506	415	447	496	4193
1023	Pre	456	328	427	455	372	444	435	434	437	3788
	Post	478	364	425	458	361	ND	416	470	469	3441
1032	Pre	346	314	398	345	346	366	390	435	377	3317
	Post	375	358	377	334	375	396	355	373	370	3313
1033	Pre	324	281	335	277	285	378	377	295	345	2897
	Post	346	323	357	316	347	328	279	383	353	3032
1035	Pre	164	ND	ND	ND	ND	ND	ND	ND	ND	164
	Post	237	ND	ND	ND	ND	ND	ND	ND	ND	237
1036	Pre	378	389	379	337	426	456	446	425	356	3592
	Post	346	331	14	378	366	284	415	445	448	3027
1042	Pre	376	305	344	ND	ND	ND	ND	ND	ND	1025
	Post	417	390	436	ND	ND	ND	ND	ND	ND	1243

Table J-1 (Continued)

Subject No.	Pre/ Post	Level									
		1	2	3	4	5	6	7	6/2	6/3	Total
1043	Pre	256	298	355	376	335	306	386	ND	308	2620
	Post	241	334	373	390	354	339	375	384	329	3119
1046	Pre	378	367	278	408	409	398	379	416	346	3379
	Post	405	387	285	456	458	397	436	394	316	3534
1052	Pre	254	275	274	227	248	ND	ND	ND	ND	1278
	Post	367	376	316	343	368	ND	ND	ND	ND	1770
1053	Pre	227	154	199	295	287	201	244	225	ND	1832
	Post	186	154	112	196	195	190	309	254	ND	1596
1055	Pre	265	214	340	297	314	309	375	316	337	2767
	Post	198	308	306	314	356	335	339	277	219	2652
1056	Pre	239	190	196	242	269	317	238	307	242	2240
	Post	245	222	273	256	286	282	-223	296	289	1926
1062	Pre	438	336	456	-21	376	475	352	446	417	3275
	Post	388	ND	480	507	387	522	468	500	439	3691
1063	Pre	316	317	274	299	292	353	266	326	346	2789
	Post	327	275	333	348	317	283	348	336	296	2863
1065	Pre	438	376	391	458	497	432	498	497	481	4068
	Post	438	429	415	385	485	444	523	484	534	4137
1072	Pre	368	338	354	335	378	386	387	366	367	3279
	Post	346	348	376	347	396	367	311	305	389	3185
1073	Pre	309	135	289	305	220	319	123	306	224	2230
	Post	184	195	248	309	294	274	274	176	327	2281
1075	Pre	396	374	356	366	298	436	367	397	383	3373
	Post	407	367	406	443	455	446	406	326	258	3514
1076	Pre	259	359	278	396	385	334	318	388	355	3072
	Post	341	309	302	336	366	367	405	318	369	3113
1082	Pre	241	247	344	325	338	250	284	255	255	2539
	Post	294	245	278	191	276	308	286	297	247	2422

Table J-1 (Continued)

Subject No.	Pre/ Post	Level									
		1	2	3	4	5	6	7	6/2	6/3	Total
1092	Pre	351	335	386	378	392	442	376	386	417	3463
	Post	318	348	354	367	398	334	384	379	429	3311
1093	Pre	315	233	306	267	294	384	325	404	266	2794
	Post	328	316	387	370	336	337	404	376	357	3211
1095	Pre	245	238	289	346	364	308	388	369	318	2865
	Post	280	337	398	288	287	328	329	384	265	2896
1096	Pre	309	317	264	344	368	357	447	306	286	2998
	Post	247	334	299	366	ND	68	286	276	276	2152
1102	Pre	176	267	133	287	315	299	271	308	359	2415
	Post	208	256	237	318	337	ND	294	337	378	2365
1105	Pre	217	218	205	186	307	275	287	280	225	2200
	Post	176	217	207	223	150	205	182	267	228	1855
1106	Pre	255	375	266	323	358	395	405	385	378	3140
	Post	247	337	336	406	308	358	284	386	347	3009
1112	Pre	188	257	298	296	308	227	336	326	314	2550
	Post	290	215	194	265	247	304	204	225	326	2270
1113	Pre	277	284	354	348	314	317	287	342	325	2848
	Post	278	276	344	342	326	366	369	388	316	3005
1116	Pre	286	343	377	322	417	434	373	395	420	3367
	Post	276	397	375	407	409	422	455	436	435	3612
1122	Pre	309	389	385	333	419	430	396	378	174	3213
	Post	348	337	367	408	342	387	479	465	223	3356
1123	Pre	98	254	164	277	263	233	277	273	279	2118
	Post	163	327	195	337	318	243	294	234	266	2377
1125	Pre	377	378	378	ND	ND	ND	ND	ND	ND	1133
	Post	377	368	355	ND	ND	ND	ND	ND	ND	1100
1132	Pre	223	235	336	207	329	372	337	282	256	2577
	Post	228	217	217	248	308	167	358	303	206	2252

Table J-1 (Continued)

Subject No.	Pre/ Post	Level									
		1	2	3	4	5	6	7	6/2	6/3	Total
1133	Pre	358	254	337	337	287	297	377	408	414	3069
	Post	367	304	198	346	ND	336	294	314	286	2445
1135	Pre	189	347	347	368	369	298	379	312	359	2968
	Post	313	344	248	396	317	327	338	288	400	2971
1136	Pre	331	345	315	375	387	338	358	276	351	3076
	Post	246	288	307	236	382	ND	386	324	306	2475
1142	Pre	388	406	341	454	465	477	492	474	536	4033
	Post	414	430	398	454	456	496	467	469	497	4081
1143	Pre	125	377	376	338	394	403	386	330	383	3112
	Post	311	316	256	367	313	358	288	354	338	2901
1152	Pre	398	380	426	365	445	447	478	446	429	3814
	Post	408	384	266	417	415	375	423	389	447	3524
1153	Pre	417	437	413	396	426	424	401	461	481	3856
	Post	365	415	438	426	455	474	505	458	373	3909
1155	Pre	184	329	293	255	344	ND	ND	ND	ND	1405
	Post	309	226	288	380	366	ND	ND	ND	ND	1569
1156	Pre	199	278	305	218	244	293	296	235	285	2353
	Post	242	263	213	323	348	216	204	289	252	2350
1163	Pre	209	177	225	254	298	168	288	258	276	2153
	Post	ND	213	189	275	225	165	ND	299	257	1623
1165	Pre	422	345	418	383	444	361	409	450	413	3645
	Post	405	409	467	428	401	358	370	467	452	3757
1166	Pre	348	290	317	286	252	308	308	356	338	2803
	Post	296	326	326	334	338	262	358	384	315	2939
1172	Pre	298	156	326	296	367	305	299	322	408	2777
	Post	346	314	323	326	353	343	276	443	285	3009

Table J-1 (Continued)

Subject No.	Pre/ Post	Level									
		1	2	3	4	5	6	7	6/2	6/3	Total
1173	Pre	324	382	389	345	377	397	337	373	376	3300
	Post	416	420	446	446	378	387	332	327	425	3577
1182	Pre	187	295	218	237	244	305	287	264	339	2376
	Post	298	235	278	280	303	228	306	307	289	2524
1183	Pre	378	305	406	427	418	357	423	456	307	3477
	Post	ND	357	387	214	374	416	376	370	296	2790
1185	Pre	276	317	201	311	328	308	323	338	357	2759
	Post	319	359	178	339	328	275	325	366	384	2873
1186	Pre	333	271	351	375	376	347	369	369	364	3155
	Post	339	368	349	352	345	365	335	347	411	3211
1192	Pre	347	298	254	266	368	364	358	398	338	2991
	Post	307	305	326	398	328	341	336	266	366	2973
1195	Pre	208	395	324	395	358	307	347	322	297	2953
	Post	322	287	366	247	379	366	357	407	335	3066
1196	Pre	124	217	325	333	248	312	270	264	278	2371
	Post	153	229	296	247	325	271	245	ND	317	2083
1203	Pre	224	360	276	355	348	335	312	418	398	3026
	Post	253	327	297	298	388	346	394	394	388	3085
1205	Pre	401	375	396	313	360	366	454	487	346	3498
	Post	426	437	427	382	465	426	475	518	417	3973
1206	Pre	183	296	203	245	267	224	259	296	325	2298
	Post	168	216	275	276	216	318	325	335	266	2395

Table J-1 (Continued)

Subject No.	Pre/ Post	Level											
		1/6	2/6	3/6	4/6	5/6	6/6	7/6	6/12	6/25	6/50	6/100	Total
2012	Pre	208	280	257	279	294	278	ND	175	ND	ND	ND	1771
	Post	159	267	248	141	310	266	ND	231	ND	ND	ND	1622
2013	Pre	286	277	266	315	304	225	353	327	325	214	ND	2892
	Post	334	347	287	268	353	335	299	319	259	267	ND	3068
*2015	Pre	274	336	327	337	384	395	413	418	ND	ND	ND	2884
	Post	360	397	377	327	397	368	305	418	ND	ND	ND	2949
*2016	Pre	337	266	225	ND	ND	ND	ND	ND	ND	ND	ND	828
	Post	198	298	268	ND	ND	ND	ND	ND	ND	ND	ND	764
2022	Pre	136	252	217	228	257	286	277	312	261	ND	ND	2226
	Post	106	236	281	185	138	279	244	182	222	ND	ND	1873
*2023	Pre	308	ND	353	410	396	ND	ND	ND	ND	ND	ND	1467
	Post	295	319	325	347	406	ND	ND	ND	ND	ND	ND	1692
*2025	Pre	312	248	320	ND	ND	ND	ND	ND	ND	ND	ND	880
	Post	297	269	344	ND	ND	ND	ND	ND	ND	ND	ND	910
2026	Pre	316	176	285	ND	348	335	277	228	218	312	335	2830
	Post	277	295	216	228	279	326	296	250	269	297	349	3082
2032	Pre	268	397	427	345	387	448	373	394	362	398	428	4227
	Post	387	242	367	411	335	386	447	425	437	365	426	4228
2033	Pre	384	346	396	397	399	438	ND	418	423	414	416	4031
	Post	414	425	385	418	412	433	ND	384	438	366	446	4121
2035	Pre	423	408	366	327	406	408	ND	357	437	466	ND	3598
	Post	327	407	365	400	388	416	ND	417	457	517	ND	3694
2036	Pre	274	300	294	414	367	ND	ND	ND	ND	ND	ND	1649
	Post	312	277	338	276	356	ND	ND	ND	ND	ND	ND	1559
*2042	Pre	235	377	324	400	385	319	ND	ND	ND	ND	ND	2040
	Post	312	358	395	ND	387	408	ND	ND	ND	ND	ND	1860

Table J-1 (Continued)

Subject No.	Pre/ Post	Level											
		1/6	2/6	3/6	4/6	5/6	6/6	7/6	6/12	6/25	6/50	6/100	Total
2052	Pre	315	346	388	387	375	374	325	305	438	297	398	3948
	Post	277	335	348	384	368	326	335	388	425	433	421	4040
2053	Pre	224	256	84	190	286	125	ND	191	123	269	ND	1748
	Post	230	188	67	243	249	96	ND	164	ND	206	ND	1443
*2055	Pre	400	ND	ND	449	434	378	ND	ND	439	458	485	3043
	Post	419	ND	ND	ND	487	477	ND	ND	465	456	493	2797
*2056	Pre	390	404	359	395	346	440	ND	349	376	455	470	3984
	Post	328	365	386	410	408	422	ND	418	447	448	ND	3632
2062	Pre	269	228	320	204	222	299	ND	228	289	326	ND	2385
	Post	245	186	213	ND	307	346	ND	263	300	351	ND	2211
*2063	Pre	ND	286	243	206	-291	280	ND	321	361	ND	ND	1406
	Post	ND	274	350	317	296	357	ND	ND	ND	ND	ND	1594
2065	Pre	400	408	378	408	404	387	ND	457	416	377	ND	3635
	Post	403	338	419	427	428	398	ND	369	416	416	ND	3614
*2066	Pre	244	387	368	398	297	285	369	412	435	407	457	4059
	Post	379	399	327	348	418	365	418	396	357	455	366	4228
2072	Pre	279	286	382	299	ND	ND	ND	237	317	ND	ND	1800
	Post	348	412	293	352	373	346	ND	ND	258	277	ND	2382
2073	Pre	178	257	125	ND	178	273	ND	293	286	294	339	2223
	Post	209	205	219	235	237	308	192	336	322	275	259	2797
2075	Pre	396	306	ND	ND	417	459	ND	484	ND	ND	ND	2062
	Post	386	ND	ND	417	456	508	ND	488	ND	ND	ND	2255
2076	Pre	392	345	268	316	357	371	ND	294	ND	425	ND	2768
	Post	353	ND	423	458	348	434	ND	387	ND	398	ND	2801
*2085	Pre	439	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	439
	Post	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND

Table J-1 (Continued)

Subject No.	Pre/ Post	Level											
		1/6	2/6	3/6	4/6	5/6	6/6	7/6	6/12	6/25	6/50	6/100	Total
2086	Pre	398	356	417	336	429	355	294	418	467	468	425	4363
	Post	399	324	377	368	456	449	426	367	358	506	497	4527

* These subjects also had PAB data from exposures that did not follow the normal pathway throught the matrix. This data is shown in Table J-2

Table J-2

Subject No.	Pre/ Post	Level																	
		0/12	1/12	2/12	2/25	2/50	3/12	3/13	3/25	4/12	4/25	5/12	6/5	6/8	6/9	6/20	Double Hearing Protection	Double Hearing Protection	Total
2015	Pre												425						425
	Post												439						439
2016	Pre			300	299	318													917
	Post			309	ND	351													660
2023	Pre				377			393	260	216	383	ND							1629
	Post				405			404	427	350	337	387							2310
2025	Pre			268	317	306													891
	Post			296	245	266													807
2042	Pre																2/6-345		345
	Post																2/6-ND		ND
2055	Pre	417	424	351			364								386				1942
	Post	445	465	468			407								451				2236
2056	Pre			417			298										!		715
	Post			429			388												817
2063	Pre																3/6-321		321
	Post																3/6-ND		ND
2066	Pre	328	348													ND	1/6-315		991
	Post	359	410													357	1/6-296		1422
2075	Pre													464			6/12-489		953
	Post													397			6/12-403		800
2076	Pre															431	2/6-ND	3/6-340	681
	Post															364	2/6-304	3/6-367	1035
2085	Pre	426	405																831
	Post	426	445																871

Note: In all cases, Second-Level Hearing Protection was worn. The PAB scores used in the data analysis was from the exposure when First-Level Hearing protection was worn.

APPENDIX K

BIBLIOGRAPHY

BLAST OVERPRESSURE STUDIES

Auditory and Nonauditory Effects
(Freefield and Reverberant Blast Waves)

Contract No. DAMD-17-88-C-8141
WALK-UP STUDY
June 21, 1989 to June 10, 1993

and

Contract No. DAMD-17-93C-3101
BLAST OVERPRESSURE STUDIES

THROUGH SEPTEMBER 1996

Blast Overpressure Studies
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