AD-A280 240

AD_____

CONTRACT NO: DAMD17-88-C-8141

TITLE: BLAST OVERPRESSURE STUDIES WITH ANIMALS AND MAN

SUBTITLE: WALK-UP STUDY

DTIC
ELECTE
JUN 14 1994
S B D

PRINCIPAL INVESTIGATOR: Daniel L. Johnson, Ph.D.

CONTRACTING ORGANIZATION: EG&G Special Projects
Biophysics Operation
2450 Alamo Avenue, S.E.
P.O. Box 9100
Albuquerque, New Mexico 87119-9100

REPORT DATE: October 31, 1993

265 pg

TYPE OF REPORT: Final Report, Task Order 1

94-18183

PREPARED FOR: U.S. Army Medical Research and
Development Command, Fort Detrick
Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

UNCLASSIFIED 2

94 6 13 075

AD_____

CONTRACT NO: DAMD17-88-C-8141

TITLE: BLAST OVERPRESSURE STUDIES WITH ANIMALS AND MAN

SUBTITLE: WALK-UP STUDY

PRINCIPAL INVESTIGATOR: Daniel L. Johnson, Ph.D.

CONTRACTING ORGANIZATION: EG&G Special Projects
Biophysics Operation
2450 Alamo Avenue, S.E.
P.O. Box 9100
Albuquerque, New Mexico 87119-9100

REPORT DATE: October 31, 1993

TYPE OF REPORT: Final Report, Task Order 1

PREPARED FOR: U.S. Army Medical Research and
Development Command, Fort Detrick
Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY *(Leave blank)*

2. REPORT DATE
31 October 1993

3. REPORT TYPE AND DATES COVERED
Final, Task Order I

4. TITLE AND SUBTITLE
Blast Overpressure Studies with Animals and Man

Subtitle: Walk-Up Study

5. FUNDING NUMBERS
Contract No.
DAMD17-88-C-8141

62787A
3M162787A878.AA
WUDA315004

6. AUTHOR(S)
Daniel L. Johnson, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
EG&G Special Projects
Biophysics Operation
2450 Alamo SE, P.O. Box 9100
Albuquerque, New Mexico 87119-9100

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research & Development Command
Fort Detrick
Frederick, Maryland 21702-5012

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES
For the period of time 6/1/88 - 9/30/93

12a. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

The U.S. Army needs realistic safe limits for exposure to impulse noise produced by heavy weapons. Impulse noise limits, based on data from small arms, may be overly conservative. In order to define new limits for heavy weapons, this systematic 5-year study of the effects of high-intensity impulse noise on human volunteers was undertaken. The number of impulses, the peak pressure levels, and spectral distributions of energy of heavy weapon-like impulses were varied systematically. Five major groups of 273 volunteers were given a series of exposures to one of three impulse types and to three types of hearing protection. The impulse spectrum was varied by changing the distance between the volunteer and an explosive detonation. The peak pressure level was varied in 3-dB steps by changing the weight of the explosive charge. The number of impulses per day was 6, 12, 25, 50, or 100. Volunteers wore hearing protection for all exposures. After each exposure, the amount of TTS, if any, was determined. Each volunteer started with an exposure of six impulses at the lowest intensity. If the TTS was less than 15 dB, the subject received six impulses at the next higher level

14. SUBJECT TERMS
Noise induced hearing loss; temporary threshold shift of hearing (TTS); RA III; Volunteers

15. NUMBER OF PAGES

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

DD FORM 1473

19. ABSTRACT (Continued)

the next day. This continued through all intensities. Then the number of impulses was increased using the maximum intensity permitted by non-auditory injury limits. The first group, using an earmuff maximum intensity permitted by non-auditory injury limits. The first group, using an earmuff as a protective device, completed all exposures. The peak sound pressure levels varied from 172 to 191 dB with an A-duration of approximately 3 ms. No significant TTS (in excess fo 25 dB) was observed for any condition.

The second group, using an earmuff with controlled leaks, completed the same exposures as the first group. In this case, only one of 65 subjects had a significant TTS. This was from 100 shots at 191 dB. Using the same protection, the third group was exposed to impulses with peak levels from 178 to 196 dB and with an A-duration of 800 sec. A considerable number of subjects had significant TTS once the peak level exceeded 187 dB. Continuing with the same leaking muff, the fourth group was exposed to impulses whose peak SPL varied from 175 to 193 dB and whose average A-duration was 1.5 ms. Again, there were cases of significant TTS once the peak level exceeded 187 dB. Using the impulses of group 4, the final group was tested with earplugs with a hole through them. Compared to the leaking muffs, these plugs were completely unsatisfactory. Significant TTs started occurring at SPL levels as low as 178 dB. Except for the perforated plugs, the majority of the subjects were willing to be exposed up to the threshold set by non-auditory considerations. Results of acceptability questionnaires and medical examinations are also included.

Accession For
NTIS GRA&I ☑
DTIC TAB ☐
Unannounced ☐
Justification
By
Distribution/
Availability Codes
Dist | Avail and/or Special
A-1

LIST OF PERSONNEL
TASK ORDER 1

1. Daniel L. Johnson, Ph.D., Principal Investigator
2. Donald R. Richmond, Ph. D., Principal Investigator's Alternate
3. Geraldine Lucero, Audiometric Technician
4. Roy Doyal, Programmer
5. Lewis West, Explosives Supervisor
6. Scott Carter, Explosives Technician
7. George Shepler, Electronics Technician
8. Bruce Moore, Photographer
9. Allie Shaw, Shepherd
10. William Hicks, Shepherd

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

_____ Where copyrighted material is quoted, permission has been obtained to use such material.

_____ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

__X__ Citations of commercial organizations and trade names in this report do not constitute an official Department of the Army endorsement or approval of the products or services of these organizations.

_____ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

__X__ For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45CFR46.

_____ In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

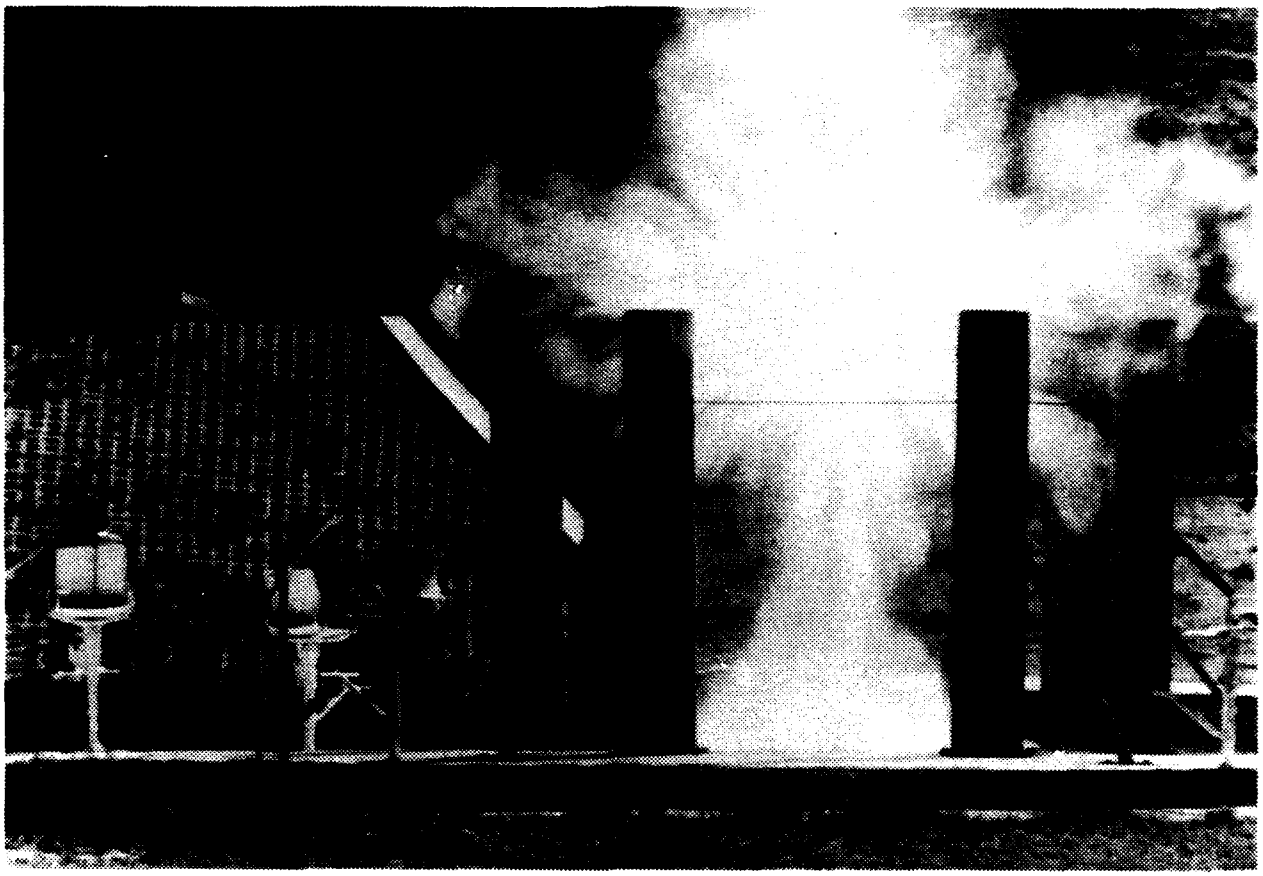
Daniel L Johnson 10/29/93

PI Signature Date

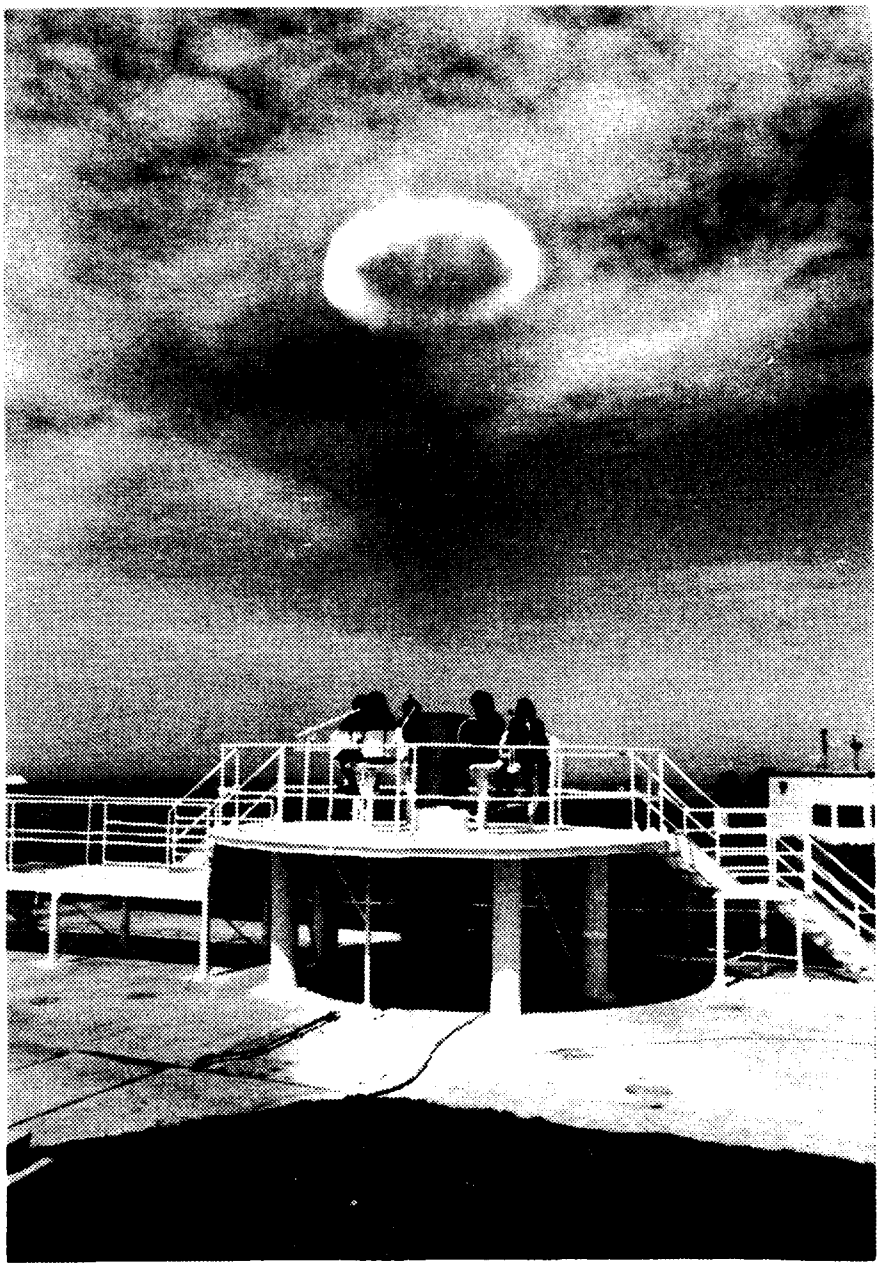
This work was supported by the U. S. Army Medical Research and Development Command under Contract No. DAMD17-88-C-8141.

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

In the conduct of this research, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by 45 CFR 46 and 32 CFR 219 (Protection of Human Subjects).



Typical exposure of Army volunteers to the 5-meter distance.



Typical exposure of Army volunteers using the mortar simulator. Subjects are located at the 1-m distance. The firing seen is not normally visible except by photography.

TABLE OF CONTENTS

Section		Page
I.	INTRODUCTION	1
	A. BACKGROUND	1
	B. DISCUSSION OF THE "WALK-UP" STUDY PARADIGM	7
	C. TEST SUMMARY	7
II.	METHODS	13
	A. GENERAL	13
	B. VOLUNTEERS	13
	C. PROCEDURES	15
	D. INSTRUMENTATION	19
	E. DATA ANALYSIS	20
	F. MEDICAL ASPECTS	20
	1. Screening Evaluations	20
	2. Entrance and Exit Evaluations	21
	3. Medical Monitoring	21
	4. Laryngoscopic Examinations	22
	5. Medical Consultative Services	23
	G. PROTOCOL UPDATES	23
	1. Addendum 1 - Approved 7 April 1990	23
	2. Addendum 2 - Approved November 1990	24
	3. Addendum 3 - Approved 24 June 1991	24
	4. Addendum 4 - Approved 18 September 1991	24
	5. Addendum 5 - Approved 6 April 1992	24
	6. Addendum 6 - Approved 6 July 1992	25
	7. Addendum 7 - Approved 27 January 1993	25
	8. Revision 1 - Approved 12 April 1993	26
III.	RESULTS	33
	A. OVERVIEW OF ALL TESTS	33
	1. 5-m Distance, Study Conditions "B" and "M"	33
	2. 1-m Distance, Study Condition "D"	33
	3. 3-m Distance, Study Condition "C"	33
	4. 3-m Distance, No-Countdown Study	33
	5. 3-m Distance, Perforated Ear Plug Study Condition "P"	34

TABLE OF CONTENTS (Continued)

Section		Page
B.	ATTENUATION OF HEARING PROTECTORS USED	34
	1. RACAL® Muff	34
	2. RACAL® Modified Muff	35
	3. E.A.R.® Foam Plug	37
	4. Perforated Plug	38
C.	AUDITORY	39
	1. 5-m Distance, Unmodified Muff, Study Condition "B"	39
	a. Summary of Auditory Failure	39
	b. Matrix Status	39
	c. Mean TTS vs Exposure Condition	39
	2. 5-m Distance, Modified Muff, Study Condition "M"	40
	a. Summary of Auditory Failures	40
	b. Matrix Status	42
	c. Mean TTS vs Exposure Condition	42
	3. 1-m Distance, Modified Muff, "D"	42
	a. Summary of Audiometric Failures	42
	b. Matrix Status	45
	c. Mean TTS vs. Exposure Condition	45
	4. 3-m Distance, Modified Muff, Study Condition "C"	45
	a. Summary of Audiotory Failures	45
	b. Matrix Status	47
	c. Mean TTS vs. Exposure Condition	47
	5. No-Countdown, 3-m Distance, Modified Muff	48
	a. General	48
	b. TTS Comparisons	48
	6. 3-m Distance, Perforated Plugs, Study Condition "P"	49
	a. General	49
	b. Status of the Matrix	51
	c. TTS Comparisons	51
D.	NON-AUDITORY AND OTHER	51
	1. 5-m Distance, Unmodified Muff	51
	a. Non-Auditory Injury	51
	b. Acceptability Charts/Elective Failures	52
	c. Exit Questionnaires	53
	d. Rank Order Charts	56
	e. Medical Data	56
	2. 5-m Distance, Modified Muff	58
	a. Non-Auditory Injury	58
	b. Acceptability Charts/Elective Failures	59
	(1) Questionnaire 1	59
	(2) Questionnaire 2	59

TABLE OF CONTENTS (Continued)

Section					Page
				c. Rank-Ordering of Acceptability of Levels 2, 3, 4, 5, and 6 Compared to Levels 1 and 7	59
				d. Exit Questionnaire	61
				e. Medical Data	61
			3.	1-m Distance, Modified Muff	61
				a. Non-Auditory Injury	61
				b. Acceptability/Elective Failures	62
				c. Exit Questionnaires	63
				d. Rank-Order Charts	63
				e. Medical Data	63
			4.	3-m Distance, Modified Muff	63
				a. Non-Auditory and Other	63
				b. Acceptability/Elective Failures	64
				c. Rank Order Charts	65
				d. Medical Data	66
			5.	3-m Distance, Modified Muff, No-Countdown	66
				a. Non-Auditory Injury	66
				b. Acceptability/Elective Failures	66
			6.	3-m Distance, Perforated Muff	66
				a. Non-Auditory Failures	66
				b. Acceptability/Elective Failures	67
				c. Rating of Levels	68
				d. Exit Questionnaires	68
				e. Medical Data	68
	E.	OTHER FINDINGS			68
		1.	Chemical Defense Gear		69
		2.	Eardrum Reddening		70
		3.	Earmuff Movement		71
	F.	BLAST LEVELS AND WAVEFORMS			72
	G.	RESULTS OF PRE- AND POST-AUDIOGRAMS			74
IV.	DISCUSSION				120
	A.	AUDITORY			120
		1.	Discussion of Each Distance		120
				a. 5-m Distance, "B", Unmodified Muff	120
				b. 5-m Distance, "M", Modified Muff	120
				c. 1-m Distance, "D", Modified Muff	122
				d. 3-m Distance, "C", Modified Muff	122
				e. 3-m Distance, "P", Perforated Plug	122
				f. No-Countdown	123
		2.	Comparison of Study Distances		123

TABLE OF CONTENTS (Continued)

Section		Page
B.	NON-AUDITORY	124
	1. Discussion of Each Distance	124
	a. 5-m Distance, Modified and Unmodified Muff	124
	b. 1-m Distance, Modified Muff	124
	c. 3-m Distance, Modified Muff	124
	2. Comparison of Non-Auditory Effects at Different Distances	124
C.	PROPOSED SAFE LEVELS	125
D.	QUESTIONNAIRES	125
	1. 5-m Distance, Unmodified Muff	125
	2. 5-m Distance, Modified Muff	125
	3. 1-m Distance, Modified Muff	126
	4. 3-m Distance, Modified Muff	126
	5. 3-m Distance, Perforated Plug	126
	6. Comparison of All Distances	126
E.	OTHER ITEMS	127
	1. General	127
	a. MMPI	127
	b. Asteroids	127
	c. Otoacoustic Emissions	127
	d. Earmuff Movement	128
V.	CONCLUSIONS	135
VI.	RECOMMENDATIONS	137
REFERENCES		139
LIST OF PUBLICATIONS AND PRESENTATIONS		143

LIST OF APPENDICES

Appendix		Page
A.	Typical Volunteer Consent Form and Registry Data Sheet	A-1
B.	Blast Overpressure Measurement Procedures	B-1
C.	Determining Allowable Intensity Sequence for a Given Distance and Determining the Sequence of Exposures for an Individual	C-1
D.	Determining Critical Threshold Shift	D-1
E.	Summary of Each Subject's Path Through the Matrix	E-1

LIST OF FIGURES

Table **Page**

Section I

I-1 Representation of typical Friedlander blast wave with nearly instantaneous rise from ambient and exponential decay. The calculation of A-impulse is illustrated. The B-duration is from MIL-STD-1474B 9

I-2 Blast overpressure of some current weapons as it relates to the Z-curve of MIL-STD-1474 10

I-3 Hypothetical form of the injury surface for Friedlander type blast wave 11

I-4 Non-auditory exposure limits 12

Section II

II-1 Diagram of typical subject positioning re: blast source 27

II-2 5-meter setup 28

II-3 1-meter setup 28

II-4 A. The mortar system (side view) 29

II-4 B. The mortar system (top view) 30

II-5 Decision tree for critical TTS pass-fail decision 31

II-6 Comparison of the real ear attenuation for the standard RACAL® muff modified by eight tubes through the seal which simulated leaks, and a special plug so that sound could reach the tympanic membrane unimpeded 32

Section III

III-1 The RACAL® muff (upper) and the modified RACAL® muff with eight tubes through the right seal (lower) 76

III-2 The perforated plug (upper) and the E.A.R. foam plug (lower) 77

LIST OF FIGURES (Continued)

Section		Page
III-3	5 meter, unmodified muff. Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for each exposure condition when the standard earmuff was worn	78
III-4	Regression of TTS vs. intensity level, 5-m distance, unmodified muff, 4000 Hz, right ear	79
III-5	Summary of TTS and Its Recovery. Subjects MAA2 and MAA5, 100 shots at level 6	80
III-6	5-Meter Distance, Modified Muff. Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for each exposure condition when modified muff was worn	81
III-7	Regression of TTS vs. intensity level, 5-m distance, modified muff, 6000 Hz, right ear	82
III-8	Growth of TTS for subject DAA4	83
III-9	Summary of TTS Growth and Its Recovery for Subject DEJ5. Exposure was six shots at level 7	84
III-10	Summary of TTS and Its Recovery. Subjects DCF3, 100 shots at level 5	85
III-11	Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for each exposure condition when modified muff was worn at 1-m distance	86
III-12	Summary of failures for the 1-m distance	87
III-13	Regression of TTS vs. level for the 1-m distance, 6000 Hz, right ear	88
III-14	Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for modified muff at the 3-m distance	89

LIST OF FIGURES (Continued)

Section		Page
III-15	Summary of failures for the 3-m distance	90
III-16	Regression of TTS vs. intensity level for 3-m distance, 4000 Hz, right ear	91
III-17	Regression of TTS vs. intensity level, 3-m distance, 8000 Hz, right ear	92
III-18	Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for each condition for perforated plug, 3-m distance, 19 subjects	93
III-19	Summary of failures for Perforated Plugs	94
III-20	Regression of TTS vs. intensity level, 3-m distance, perforated muff, 3000 Hz right ear	95
III-21	Reddening of the arm facing the blast while wearing damp fatigue shirts	96
III-22	Daily medical report prepared by physician assistant/nurse practitioner	97
III-23	Percent of time vs. energy level that subjects reported some problem with mouth or throat	98
III-24	Percent of time vs. energy level subjects reported any medical problem other then nose or mouth (throat)	99
III-25	Final summary for "acceptability to train" questionnaire, acceptable/unacceptable response, 5-m distance	100
III-26	Final summary for "acceptability to train" questionnaire showing finer breakdown response, 5-m distance	101
III-27	Summary of rank ordering of acceptablity for 5-m distance	102
III-28	Percent of subjects which indicated the step from the one level to the next as the largest of the six steps	103

LIST OF FIGURES (Continued)

Section		Page
III-29	The number of times the size of the step as indicated on the horizontal axis was six units or more	104
III-30	Report of petechiae	105
III-31	Grand summary - mortar distance	106
III-32	Summary of 60 subjects - mortar distance	107
III-33	Mortar distance summary	108
III-34	Acceptability ranking for 3-m distance	109
III-35	Number of unacceptable ratings for 60 subjects, 3-m distance	110
III-36	Rank order of 3-m distance	111
III-37	Eardrum reddening rating report	112
III-38	Tympanic injection rating	113
III-39	Percent injection, right ear, 3-m distance	114
III-40	Percent injection, left ear, 3-m distance	115
III-41	Typical waveform of 5-m distance	116
III-42	Typical waveform of 3-m distance	117
III-43	Typical waveform of 1-m distance	118
III-44	Comparison of pre- and post-study hearing threshold levels of the on-test ear for 259 subjects	119
III-45	Comparison of pre- and post-study hearing threshold levels of the test ear for 259 subjects	119

Section IV

IV-1.	Conditions rejected for protection of 95%, 90%, and 80% of the population, 5-m distance, modified muff	129

LIST OF FIGURES (Continued)

Section		Page
IV-2.	Conditions rejected for protection of 95%, 90%, and 80% of the population, 1-m distance, modified muff	130
IV-3.	Conditions rejected for protection of 95%, 90%, and 80% of the population, 3-m distance, modified muff	131
IV-4.	Comparison of acceptability of the three distances vs. peak SPL for the modified muff	132
IV-5.	Comparison of the three distances on an equal energy basis. The modified RACAL® muff is used	133
IV-6.	Proposed safe peak levels vs. number of exposures for three different percents of the population not protected	134

LIST OF TABLES

Table		Page
III-1	Total Number of Test Subjects	34
III-2	Attenuation of the RACAL® muff from the PEAT tests (69 subjects)	35
III-3	Mean attenuation values for the modified RACAL® muff (right ear modified) using the PEAT baseline values for 57 subjects	36
III-4	Mean baseline attenuation values for the E.A.R.® foam plug	37
III-5	Mean baseline attenuation values for the Perforated plug	38
III-6	Summary of conditional failures 5-m Distance	39
III-7	Slope of linear regression versus intensity level for various study distances	40
III-8	Conditional failures, 5-m distance modified muff	41
III-9	Full Audiometric Failures, 5-m Distance Modified Muff	41
III-10	1-M Distance, Conditional Failures Modified Muff	42
III-11	1-m Distance, Audiometric Failures Modified Muff	44
III-12	Conditional Failures, 3-m Distance Modified Muff	46
III-13	Full Failures, 3-m Distance Modified Muff	47
III-14	Conditional Failure No-Countdown Study, 3-m Distance	48
III-15	Mean Audiometric Difference Between Countdown and No-Countdown Exposures, Post 2-Minute Audiograms	49
III-16	Conditional Failures, 3-m Distance, Perforated Plugs	49
III-17	Full-Audiometric Failures, 3-m Distance, Perforated Plugs	50
III-18	Non-Auditory Injury 5-m Distance, Unmodified Muff	51

LIST OF TABLES

Table		Page
III-19	Elective Failures 5-m Distance, Modified Muff.....	52
III-20	Volunteer Exit Questionnaire Summary.....	53
III-21	Number of positive responses to daily medical questionnaire with respect to questions on nose and questions on mouth/throat.....	57
III-22	Summation of TRUE values for medical data.....	58
III-23	Summary Acceptability Questionnaire.....	60
III-24	Summary of Elective Failures.....	61
III-25	Summary of Elective Failures.....	62
III-26	Summary of Elective Failures 3-m Distance, Modified Muff.....	64
III-27	Acceptability/Elective Failures.....	67
III-28	Subjective Response to Various Levels to Wearing the M17 Chemical Defense Suit.....	69
III-29	Earcup Movement.....	72
III-30	Average Peak Pressures and Duration for the Impulses at 5 m from the Source.....	73
III-31	Average Peak Pressures and Durations for the Impulses at 3 m from the Source.....	73
III-32	Average Peak Pressures and Durations for the Impulses at 1 m from the Source.....	74
III-33	Pre-Study and Post-Study Hearing Threshold Levels, 259 Subjects.....	75
IV-1	5-m Distance, Modified Muff. Conditions Rejected for Protection of 95%, 90%, and 80% of the Population.....	121

I. INTRODUCTION

It was the objective of this study to determine the safe limits of occupational exposure while wearing hearing protection to impulse noise characteristic of mortars and howitzers fired in the open. This introduction explains the need for this study, describes the basic approach used in the study, and summarizes the major tests accomplished. This introduction is in three parts. They are:

- Background
- Discussion of the Walk-Up Study Paradigm
- 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 as well as 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, 1966; 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 the 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 (1-6 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 non-auditory 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 non-auditory 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 USAMRDC initiated 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 protectors 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 for 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 higher frequency sound (1-6 kHz) of equal total acoustic energy (Buck, 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.

The NATO Panel VIII, "Defense Applications of Human and Biomedical Sciences," convened a Research Study Group (RSG-6: 'Effects of Impulse Noise') to study the basic problem of BOP exposure limits and to reconcile the present disparities between the various national standards (Smoorenburg, 1982). The final report of RSG-6 (NATO, 1987) summarizes the findings of the study group. It was agreed that, while there are obvious shortcomings in all national standards in assessing the risk of cannon BOP, there is no cogent reason to abandon any of the present standards. An ideal standard should address: (a) the spectral weighting of the impulse noise hazard, (b) attenuative properties of different hearing protectors, (c) the possibility of critical levels of sensitivity to noise, and (d) non-auditory hazards from impulse noise.

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, there are several factors that 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 USAMRDC 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, USAMRDC 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 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 non-auditory 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 study reported herein again are showing the conservative nature of the Z-curve for several different freefield waveforms. Over 270 subjects were used under a protocol very similar to the protocol used for the M203 study.

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 ultra-light towed 155-mm howitzer, and new shoulder-fired antitank rockets. The blast overpressure (BOP) limitations based on MIL-STD-1474C are important considerations in 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 would 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. 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 non-auditory exposure limit has been lacking.

Therefore, the general approach of this study was to use several different waveforms. Since the shapes of the waveforms are affected by distance, three separate study distances were used.

The MIL-STD-1474C deals with the possibility of non-auditory injury briefly but effectively. It states: "Higher levels than the

Z-curve are not permitted due to a possibility of other non-auditory physiological injury." Clearly, at sufficiently high levels blast can kill; but where beyond the Z-curve does the threshold of such injury lie? Numerous necropsy studies using sheep and swine as large animal models have been done to estimate human risk (Dancer et al. , 1981; TB MD 501, 1980; Richmond et al., 1981; and Vassout et al., 1984). Exposures of animals to waveforms similar to weapon BOP have been used to justify human exposure in the man-rating studies of the M198/M203 and to the UK 81-mm mortar. Investigations into the basic pathophysiology of blast injury have led to a consensus within RSG-6 that for simple freefield BOP the number of exposures, peak pressure and impulse (a function of peak pressure and A-duration) interact to determine damage to air containing organs, (Phillips et al., 1982; Vassout et al., 1984; and Yelverton et al., 1983). Observations of non-auditory damage have shown laryngeal injury to precede or accompany injury to other organs, specifically, pulmonary and gastrointestinal systems (Phillips et al., 1982; Vassout et al., 1984; and Yelverton et al., 1983). While upper respiratory injury is often not the most severe component, it is inevitably present when more significant injury occurs elsewhere. Therefore, the absence of laryngeal injury in large animals has proven to be a reliable indicator of the absence of other non-auditory injury.

If all combinations of number of exposures (N), peak pressure (P), and impulse (I) which result in similar minor laryngeal injury could be determined, a three-dimensional surface of iso-injury could be described (Figures I-3). Any point lying on the lower side of the threshold surface would be associated with the absence of any non-auditory injury. A point on the upper side of the threshold surface would be associated with the potential for laryngeal injury with the likelihood of pulmonary and/or GI injury increasing the farther the point is away from the threshold injury surface. Knowledge of this threshold injury boundary would allow a safety assessment to be made for any weapon system that generates a simple Friedlander BOP. Exposure conditions (N, P, and I) would either be on the "safe" side of the boundary and thereby permissible or on the "unsafe" side, which would carry a risk of non-auditory injury to crew members.

Using this basic framework described, a careful study to determine the threshold of non-auditory injury in two large animal species was undertaken. A graph of P vs. I some limiting lines of exposure for soldiers can be displayed. Although the effect of N on the shape and position of the P vs. I limiting curve is probably a continuous function (Figure I-3), practicality dictates that it be dealt with as shown in Figure I-4. One line defines the limits for up to 6 exposures, another for up to 25. A third line defines the absolute limit for up to 100 exposures. The Army stated that it was extremely unlikely that more than 100 exposures to such intense BOP would be desirable (or affordable) in training. These non-auditory curves may then be compared to the Z-curve of

MIL-STD-1474C. Note in Figure I-4 that there is a Z-curve region, this is because there is no constant relationship between A-impulse and B-duration, the abscissa of the non-auditory and MIL-STD graphs. There is also an area on Figure I-4 between what is now permitted and the maximum that we would allow based on non-auditory risk. It was the purpose of this study to explore that region by exposing volunteers to BOP beginning below the Z-curve of MIL-STD-1474C gradually increasing the intensity and then the number of exposures until either the non-auditory limits were reached or the soldier met one of a set of auditory failure criteria.

The auditory end points (failure criteria) used in this study were based on 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 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 under 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 just completed, these assumptions were not contradicted.

The growth of the average TTS with increasing impulse noise exposure intensity has been reported to be approximately 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). Occasional-

ly, 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 threshold, 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.

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 well 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 has been 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, further exposure at that level was stopped.

C. TEST SUMMARY

Starting in October 1989, there were five major phases of testing accomplished using three study distances and four different types of hearing protection.

1. The first phase was a 5-m distance with a duration of 3 ms. An intact RACAL® muff was used as the hearing protector with the E.A.R.® foam plug as an alternative (or a backup) in case the muff did not work for an individual.

2. The second phase was the repeat of the 5-m distance using a RACAL® muff with holes in the cushion to simulate a poorly fitted

muff with leaks around the seal. The backup to this modified RACAL® muff was a RACAL® muff without holes.

3. The third pause was a 1-m distance with a duration of less than 1 msec. This modified RACAL® muff was again worn with the unmodified RACAL® muff used as a backup.

4. The fourth phase was the 3-m distance with an appropriate duration of 1.5 msec. The modified RACAL® muff was again used with the unmodified RACAL® muff as a backup.

5. The fifth and final phase was a repeat of the 3-m distance with a perforated plug as the hearing protector. The perforated plug had a hole through it so speech sounds could easily reach the ear. The E.A.R.® foam plug was used as a backup. Testing was finished by 15 August 1993.

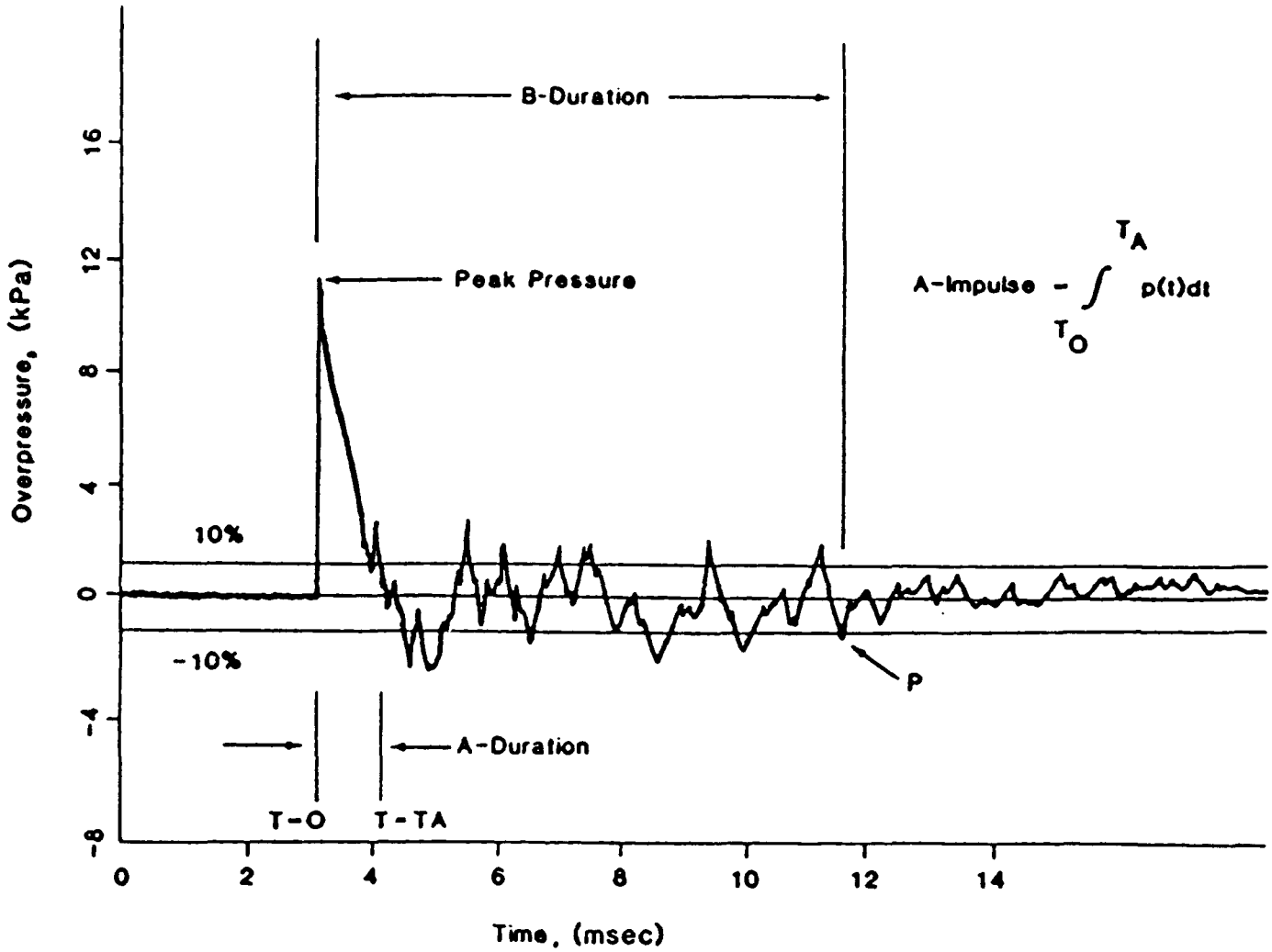


Figure I-1. Representation of a typical Friedlander blast wave with nearly instantaneous rise from ambient and exponential decay. The calculation of A-impulse is illustrated. The B-duration is from MIL-STD-1474B.

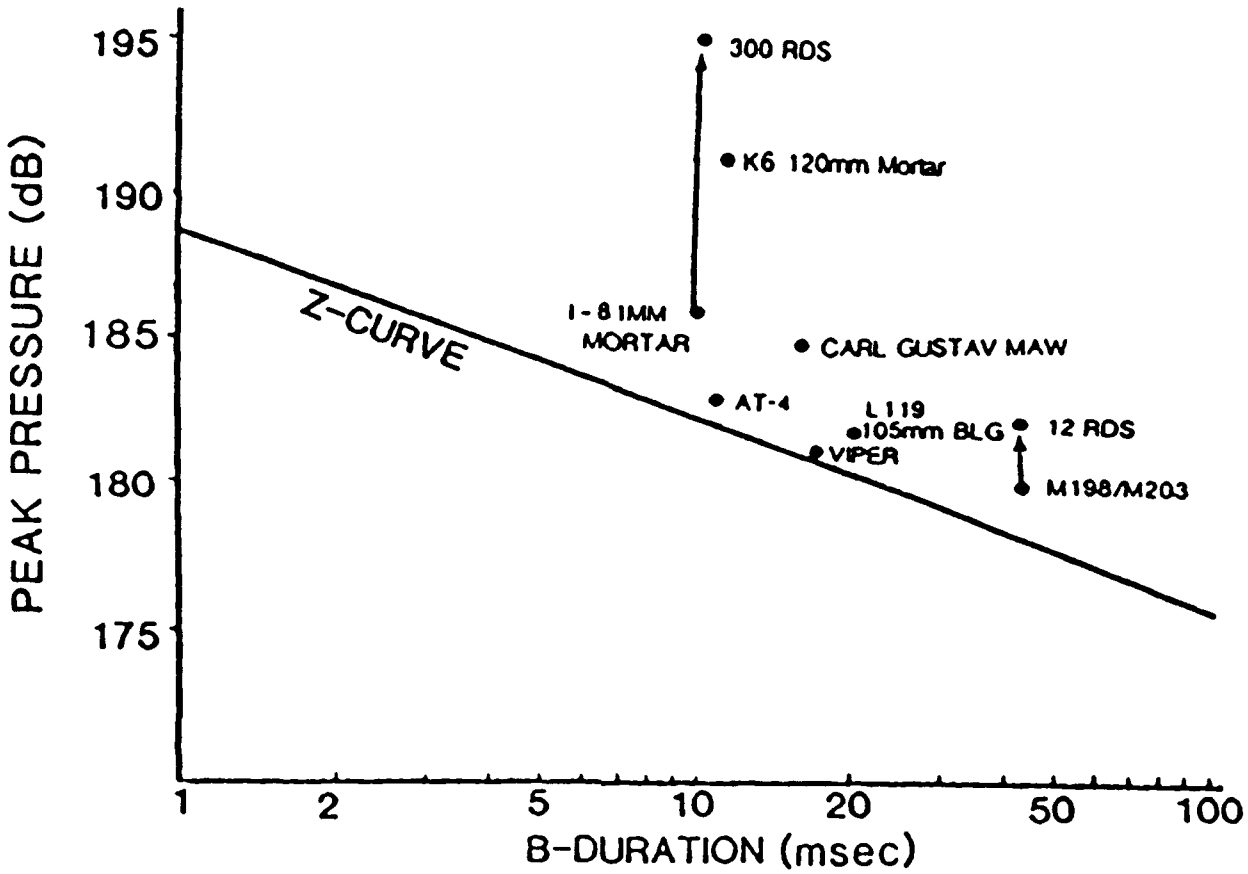


Figure I-2. Blast overpressure of some current weapons as it relates to the Z-curve of MIL-STD-1474B. Effective increase in level of increases in number is given as dB = 5 log(N).

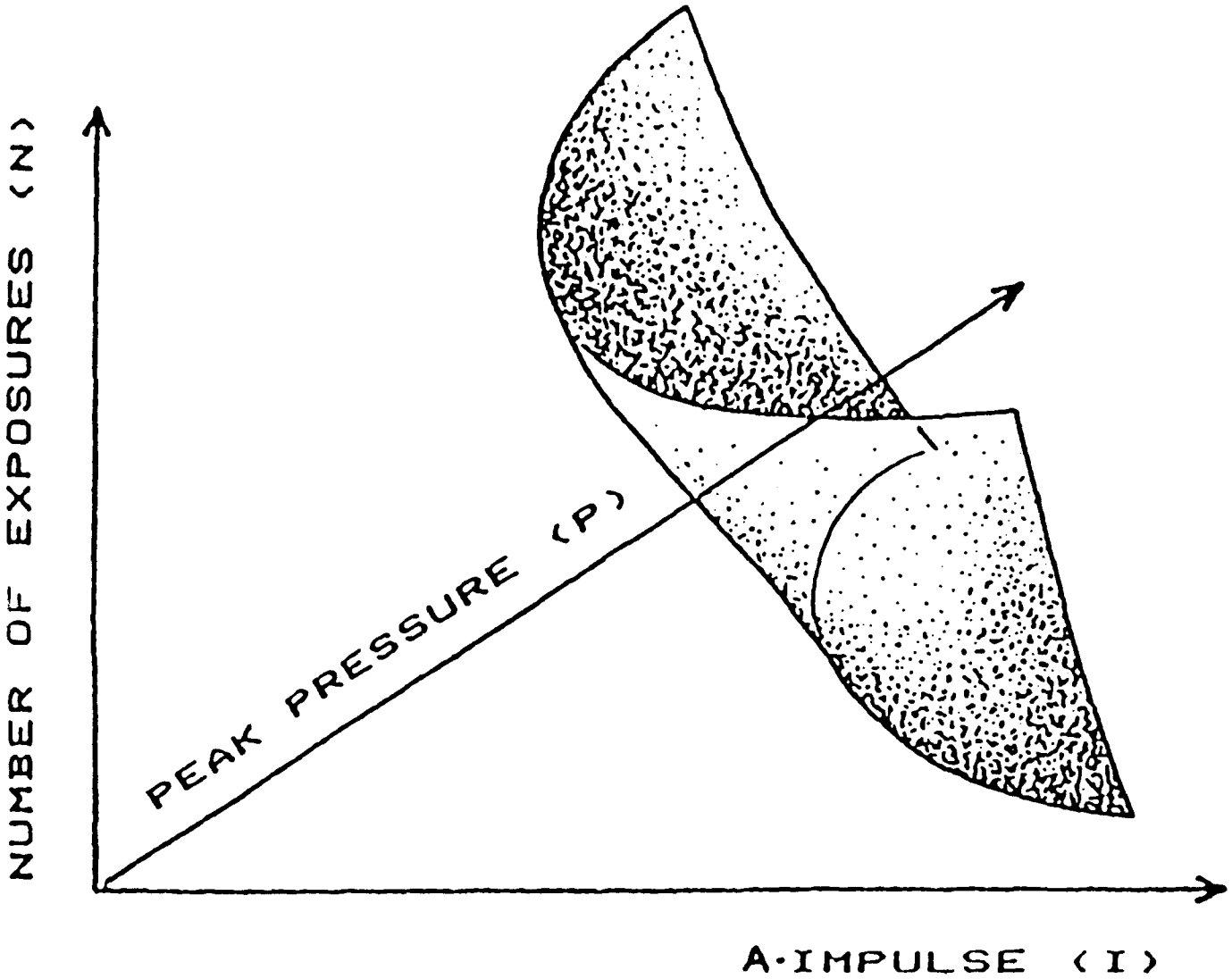


Figure I-3. Hypothetical form of the injury surface for Friedlander type blast waves.

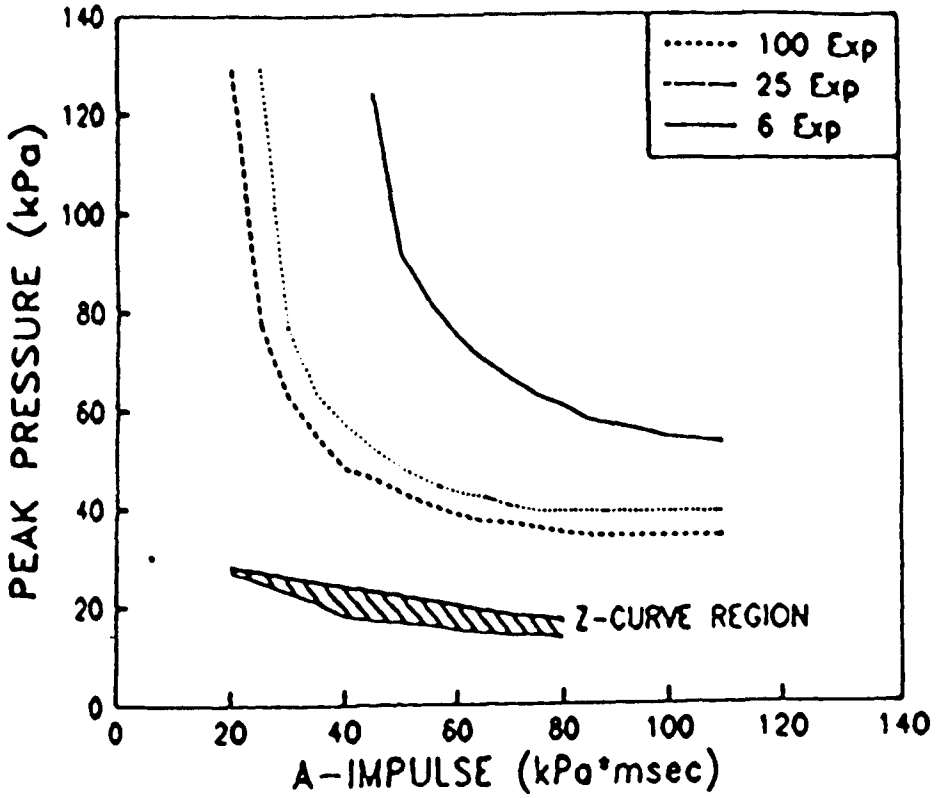


Figure I-4. Non-auditory exposure limits. The dashed line represents the limiting conditions for up to 25 exposures and the solid line the limiting conditions for 25 to 100 exposures. The cross-hatched area represents the Z-curve region assuming a triangular wave and a B-duration equal to six times the A-duration and a B-duration equal to four times the A-duration.

II. METHODS

A. GENERAL

The study was conducted at the Blast Overpressure-Kirtland Test Site (BOP-KTS) in New Mexico. Under a contract for the USAMRDC, 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 Dr. Daniel L. Johnson, Ph.D. with Dr. Donald R. Richmond, Ph.D., substituting during periods when Dr. Johnson was absent from the site. Scientific oversight was maintained by the USAMRDC contracting officer's representative of this protocol, Dr. James Patterson, Ph.D., MAJ William R. Nelson and CPT Jennifer Johnson of USAARL; and Gary Ripple, MD, and M. A. Mayorga, MD, WRAIR. The protocol used in the study was reviewed for scientific content and human use considerations both by an Institutional Review Board of EG&G and a Human Use Committee at USAMRDC. 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 Dr. James Patterson at Fort Rucker or Dr. Daniel Johnson, EG&G. EG&G provided on-site medical support and a medical monitor via a subcontract with Lovelace Medical Center.

B. VOLUNTEERS

Active duty males were asked to volunteer. Females were not recruited as the MOS's associated with intense impulse noise were closed to 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 enroute to their first unit assignment.

The request for volunteers was made to company or battalion-sized formations at approximately 5 wk 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 any time without penalty. Volunteers who were in good military and academic standing were initially screened at an Army hospital, approved by PERSCOM, for subject suitability. A goal of a total of 60 volunteers for each exposure phase was used. Volunteers were taken in groups of six and participated for a period of approximately 45 days. Initially, only one group at a time was taken. Two groups at a time were recruited by January 1990.

To further minimize the already very low risk of non-auditory 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: pneumothorax, allergic rhinitis, sinusitis, or emphysema. Each candidate was screened by 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 g uaiacswere done once during the experiment. 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 right, or experimental 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 non-experimental, 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 the experimental ear because 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 ear plugs and, where feasible, by ear plugs and ear muffs. Further, the level of the impulse noise was reduced to some extent on the left side by the "shadow" effect of the head.

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 conclusion in the study might disqualify them. Each subject was checked to ensure his ability to effectively wear E.A.R.® compressible foam ear plugs, the type of ear plugs employed 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 in the proper method of inserting the E.A.R.® 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.

Prior to graduation from training, a final selection of volunteers was made based on medical prescreening and cadre recommendations. Subjects 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 still 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 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 PI.

In addition to the military volunteers, the PI and COR(s) were permitted to experience exposures up to the levels permitted by MIL-STD-1474C. In March 1990, Drs. Johnson, Richmond, and Patterson were allowed to go to the top level for 1-shot per day. Double hearing protection was required. Pre- and post-audiograms were obtained for each exposure session. Multiple exposures on the same day were permitted for these volunteers. Medical screening was waived and laryngoscopic exams were waived.

C. PROCEDURES

For the 5-m distance, the BOP was produced by detonation of Composition C-4 explosive over a concrete pad. Two different setups were used. A quantity of C-4 in a cheese cloth bag was suspended by a nylon cord from an overhead assembly and detonated with a length of detonating cord connected to an exploding bridge wire (EBW) detonator. The detonator was inside a metal container capable of withstanding the detonation. This contained the fragments associated with the detonation process. Up to six subjects at a time were exposed at a distance 5 m from the charge as illustrated in Figure II-1. A metal pipe was positioned between each subject and the charge to deflect any debris from the explosion (Figures II-1 and II-2). Being kept at 5 feet from subjects, it did not affect the

BOP signature. For the 1-m and 3-m distances, 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 sat around the lip of the tube. See Figures II-3, II-4A and II-4B for details. For the 1-m distance, the center of the subject's ear was kept at 29 inches from the outer lip of the tube and 3 inches above the plane of the lip. For the 3-m distance, the center of the subject's right ear was kept either 6 ft 6 inches from the lip (lowest five exposure conditions) or 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 for all distances. 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 non-test ear was afforded double protection (E.A.R.® plugs and muff) except for the perforated earplug study. 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, of if the threat of lightning was present. The PASGT helmet was always worn.

Before any exposures to BOP, at least eight baseline audiograms were taken. The average and standard deviation of at least eight of these was 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 are 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.

Each volunteer was given training on the proper use of both types of hearing protectors to be used in the study before any exposures to BOP. In the initial phases of the study, at least eight attenuation tests of both earplugs and earmuffs were completed during this training. Later, the full baseline for the E.A.R.® foam plug 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 is acceptable.

The first exposure for any subject at any distance was below the level of the Z-curve of MIL-STD-1474C, Figure II-2. All overpressure measurements were made according to the recommendations of the US Army ad hoc Committee on Blast Overpressure Measurements. Overpressures were recorded at several sites 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 USAMRDC 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 starts at the lowest number (N = 6), 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. N was always set to 6, 12, 25, 50, and 100. A was set at approximately a 3-dB increase of peak level for each set 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.® 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 a 95% confidence interval of his baseline audiogram average. The subject then fit himself with either ear muffs or E.A.R.® plugs. The experimenter assisted the subject in fitting the ear muffs or ear plugs only, if necessary, to insure appropriate attenuation as indicated by his baseline tests. The efficacy of the protection was tested as follows: The real ear attenuation test (REAT) in which the difference in a subject's hearing threshold with and without a protector is used as the protector's attenuation was used for the perforated plug and the E.A.R.® foam plug.

The physical ear attenuation test (PEAT), in which the difference in an octave band sound level from a miniature microphone at the entrance to the subject's ear canal is used to predict

the protector's attenuation, was used for the RACAL® muff. Pink noise in a reverberant room was used as the noise source. This testing guarded against allowing the volunteer soldier to be exposed to the intense noise with either improperly fitted and, hence, ineffective or overly fitted, 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, but because he passes this condition, the next higher exposure condition may cause excessive TTS if his hearing protector attenuation returns to normal. The hearing protectors could be adjusted and tested until an appropriate level of noise attenuation was obtained ($\pm$ 5 dB with respect to his baseline).

The subject(s) were positioned on the exposure pad as described above. Some number (N) of charges of weight (W) were set off at 1-minute intervals. Beginning at approximately 2 minutes following the exposure, the ATA was repeated to determine any temporary threshold shift (TTS) which might have been induced by noise exposure. The subject's TTS was determined at 20 minutes and 1 hour after exposure. If the TTS at 1 hour was back to baseline ($\pm$10 dB), then the subject was excused from further audiometry. Otherwise, an ATA was performed at 2 hours and, subsequently, as needed. Occasionally, the 20 min or the 1 hour audiogram was used when clearly the TTS was growing with time. Then, numerous audiogram were taken to ensure that the time 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-5. 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 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 evaluation. Subjects with excessive TTS (>40 dB) and subjects with TTS that grew with time were also dropped from further exposures.

The fundamental audiometric failure crierion was set as a TTS of 25 dB at any frequency. (For subjects with audiometric variability, $\geq$3 dB, a small adjustment was made that elevated this level (or 2 dB), see Appendix D for details.)

In order not to unduly over expose subjects who werejust 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 $\geq$2 dB, a small adjustment was made that elevated this level from 0 to 2 dB more. Again, see

Appendix D.) When a subject was a conditional failure, his next step was to a lower intensity at double the number of shots.

Routine laryngoscopic examinations were initially given after all exposure conditions closest to the non-auditory limits for 6 and 25 blasts and at all conditions one energy step below these limit conditions. Additional examinations could be given at any condition that the investigators or medical monitors deemed prudent. A positive laryngoscopic finding on these exams resulted in a repeat exposure starting one energy level below th e one thatresulted in a positive finding. Two positive laryngoscopic exams at the same exposure conditions or adjacent conditions resulted in a non-auditory failure in the lower energy condition. A non-auditory failure resulted in that subject being precluded from any exposures at the same or higher intensities.

After negative results in the early stages of the 5-m distance, the IRB allowed this intermediate tests to be dropped if all the first 12 subjects passed these tests at any study distance. Since these exams were negative at all study distances, only the pre- and post-exposure overall study participation laryngoscopic exams were taken on most of the subjects.

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. INSTRUMENTATION

The collection of primary data in this study was accomplished using a custom-designed data acquisition and analysis system (DAAS). It consisted of a Hewlett-Packard 1000 minicomputer system linked to a Hewlett-Packard 9826 desk top computer. The 9826 controlled the acquisition of blast exposure signatures through four channels of analog-to-digital (A-D) conversion. The A-D converters sampled the output of blast gauges manufactured by PCB at 250,000 samples per channel. The time histories of each detonation were transferred to the HP 1000 for analysis and archival storage. Data were archived on 9-track digitaltapeor a write-once-read many optical disk.

All audiometric data were acquired directly by the HP 1000. The audiometric procedure, modified Bekesy tracking, was set up to test six volunteers simultaneously. The system was patterned after the system used on the M-198 study (Mozo et al., 1984; Patterson et al., 1985). The HP 1000 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 were TDH-49 elements mounted in a David-Clark 9AN/2 earmuff 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 1/2-inch B&K microphone that was 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 earmuff attenuation test was accomplished in a reverberant room using a pair of miniature microphones for each volunteer. The microphone output was amplified and input to an HP spectrum analyzer that was interfaced to the HP 1000. The difference in octave band levels with and without the RACAL® muff was used as the attenuation of the muff.

E. DATA ANALYSIS

For each exposure set, the blast overpressure (intensity) was recorded and expressed in terms of peak pressure (kPa), A-impulse (kPa.msec), and B-duration (msec) as detailed in MIL-STD-1474B. The overpressure was analyzed for total acoustic energy (joules/m^2), A-duration (msec), C-duration (msec), and D-duration (msec) and total area under the pressure-time history as recommended by the NATO Panel VIII RSG-6. Characteristic pressure-time histories were archived.

F. MEDICAL ASPECTS

1. Screening Evaluations

Medical screening of volunteer subjects before their traveling to Albuquerque was done to eliminate those with preexisting conditions that might be aggravated by the study conditions. Apart from the medical history, general physical examinations and additional clinical examinations that included an EKG, a single PA and lateral chest film, a forced expiratory spirogram, complete blood count, an SMA-12 or similar chemical profile, a urinalysis and stool guaiac. A laryngoscopic examination was performed and recorded on each subject by a qualified physician.

Any significant abnormalities on this screening examination 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.

Because this screening was duplicated by the entrance physicals accomplished by Lovelace, this screening was dropped in

November 1990. Only review of the medical records by an Army physician was continued.

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 by the Occupational Medicine Department at Lovelace Medical Center. This examination included the same elements as the screening examination similarly performed at a military installation. A personality test was also administered during both the entrance and exit evaluations. This test was dropped in September 1991. The results of these examinations served as a record of the physical condition of each subject at the start and the conclusion of this study period. The volunteer's records of medical examinations during the study are maintained at the BOP test site, 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 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 Clinic 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 in order 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 which resulted from previous exposure to blast.

(c). Allow each subject to express particular concerns relative to 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 to an Occupational Medicine physician at the Lovelace Medical Center for evaluation. 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 in the following manner:

a. Fiberoptic laryngoscopy was performed according to a standardized protocol after local anesthesia of the naso-pharynx.

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 have cleared. The subject received subsequent examinations of the larynx until the petechiae cleared.

5. Medical Consultative Services

Medical consultative services were provided to the subjects throughout the course of the study. Subjects who expressed a particular medical concern, especially if it related to

their continued participation in the study, had this concern 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 Lovelace Medical Center. Normally, this counseling would be accomplished on the same day. 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: return to the sequence of blast exposures; exclusion from the study; or referral to 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. PROTOCOL UPDATES

As the multi-year study progressed, certain changes to the protocol were made and approved by the local Institutional Review Board, by Fort Rucker, and ultimately by the Office of the Surgeon General's Human Use and Regulatory Affairs at Fort Detrick. Since, these changes illustrate change in the procedures, these are listed along with the dates they were effective:

1. Addendum 1. Approved 7 April 1990

The following change was made to the protocol dated March 1990. At the completion of the 5-m distance, the mortar study (1-m distance) was scheduled next. The next sequence was a repeat of the 5-m distance using a modified muff that had less attenuation. Consistent with this change, the following changes were made:

a. The use of second- and third-level protection was eliminated for this repeat of the 5-m distance. Thus, when a subject completed the exposure matrix with the modified muff, he was through with the experiment even if he had a failure at one or more conditions.

b. Only one occluded ear test of the plugs were obtained and the daily pre-exposure occluded tests were dropped.

c. The Physical Ear Attenuation Test (PEAT) baseline for the modified muff was established using as few as four measures. The muff position marked with grease pencil and the microphone was removed. The muff was kept in the same position using the mark as a guideline.

d. The 8-m distance was dropped from the study; thus, the total number of volunteers was not changed.

2. Addendum 2 - Approved November 1990

This addendum incorporated changes approved by the EG&G Special Projects Institutional Review Board Meeting of November 2, 1990. The requirement for medical examinations at the recruitment site and for intermediate laryngoscopic examinations were eliminated.

3. Addendum 3 - Approved 24 June 1991

This addendum incorporated the following changes or clarifications for the 60 subjects to be exposed to the 1-m distance, the "mortar study." These changes or clarifications were approved by the EG&G Special Projects Institutional Review Board at their meeting of 7 June 1991.

The mortar study used the modified muff as outlined in the protocol addendum 1, 1 August 1990. The use of second- and third-level protection, however, was reinstated for this mortar study. The second-level hearing protection used the unmodified RACAL® muff. The third-level hearing protection used the E.A.R.® plug. Once failure of first-level hearing protection occurred, testing with second-level hearing protection would be more efficient if it could begin before all the matrix for first-level hearing protection was finished. The change was made to allow, upon failure, use of conditions allowing second-level hearing protection before all conditions using first-level hearing protection were accomplished.

The mortar was designed and built as shown in Figures II-4A and -4B with the top 5 ft of the tube covered with Kevlar. This design, while well within the concept of the original protocol, emphasized subject safety. Specifically, all charges were loaded through a door in the lower part of the mortar tube. The subjects were elevated by approximately 6 ft and fully protected from the loading operation. The shepherd station was on a raised platform at the top of the stairs. The platform was enclosed by steel railing. Only the top part of the mortar tube visible to the subjects was covered with Kevlar.

4. Addendum 4 - Approved 18 September 1991

This change eliminated the use of before and after personality test, specifically, the MMPI test.

5. Addendum 5 - Approved 6 April 1992

This change eliminated the use of the requirement for using the daily P.E.A.T. tests of the RACAL® modified muff. This change came about from the fact that, despite any fitting assistance by the experimenter, the blast could move the muff such that the subject was required to adjust the muff. Once this occurred,

the subjects were doing all the fitting and there was no reason, in the name of safety, to check how good the fit was.

6. Addendum 6 - Approved 6 July 1992

These were protocol changes specific to the 3-m distance study condition. The changes to the protocol were reviewed and recommended for approval at the June 1992 meeting of the Institutional Review Board. The changes included:

a. The mortar simulator, as described in Addendum 3, was also used for the 3-m distance. The subjects were seated from 5.5 to 7.0 ft from the lip of the mortar. The variable distance allowed the investigators to keep the waveform consistent for increasing intensities. Chairs were on a channel that could slide to allow chairs to be adjusted to the desired distance.

b. Consistent with this change all of the procedures described in Addendum 3 were used for the 3-m distance.

7. Addendum 7 - Approved 27 January 1993

This allowed a study in which the countdown was eliminated. Specifically, the following was added:

"After any subject has successfully passed the study matrix without an auditory or non-auditory failure, they will be asked if he would participate in the "no-countdown" study matrix. It will be emphasized to the subjects that participation is entirely voluntary and they can decide to stop these additional exposures any time.

"The volunteers who elect to be exposed will keep their same subject number and will use the auditory baselines already established. The study matrix will consist of six shots at Levels 1 to 7. Only six shots at a given level will be given on any one day. No further exposure of a subject will occur once either a conditional or a hard failure occurs. During the six-shot sequence at any level, a start of a 30-second sequence during which a charge can be detonated, with the words: three, two, one, ready. After the command "Ready," the time of detonation will vary from 1 to 30 seconds. The time to reload the mortar simulator will be 40 sec or less, so the command "Ready" should be 45 seconds after the last shot. This will provide an average interval between shots of 1 min, the same as the existing study matrix. Aside from using a 30-second window in which the shot can be detonated, all other procedures established for the 3-m distance will be used."

8. Revision 1 - Approved 12 April 1993

a. Summary of the Perforated Earplug Study.

The 3-m distance was completed in April 1993. Thus, the four study distances as described in the original protocol were completed. This revision added one more study condition. This new study consisted of substituting a special triple flange perforated earplug for the modified RACAL® muff and repeating the 3-m study condition. The attenuation of the triple flange impulse ear plug was almost identical to the attenuation of the modified RACAL® muff (illustrated in Section IV). Because of the results of the 3-m distance, 3 m was considered to be an informative distance for testing the adequacy of the perforated earplug.

Second-level hearing protection consisted of the E.A.R.® foam plug. The foam plug was considered to provide adequate attenuation if it was well seated. The methods used before any of the addenda to the protocol would be reinstated. Testing would be with the foam plug in the left ear and the perforated plug in the right ear. The adequacy of attenuation of the plugs would be tested. Before exposure, an occluded test was performed on both ears before being exposed, the subject must be within his baseline established for the plug in use.

Revisions to the March 1990 protocol necessary to support the perforated ear plug study were: added to 3-m study distance 24 more subjects using perforated ear plug as first-level hearing protection; and added figure to show attenuation of perforated ear plug (see Figure II-6).

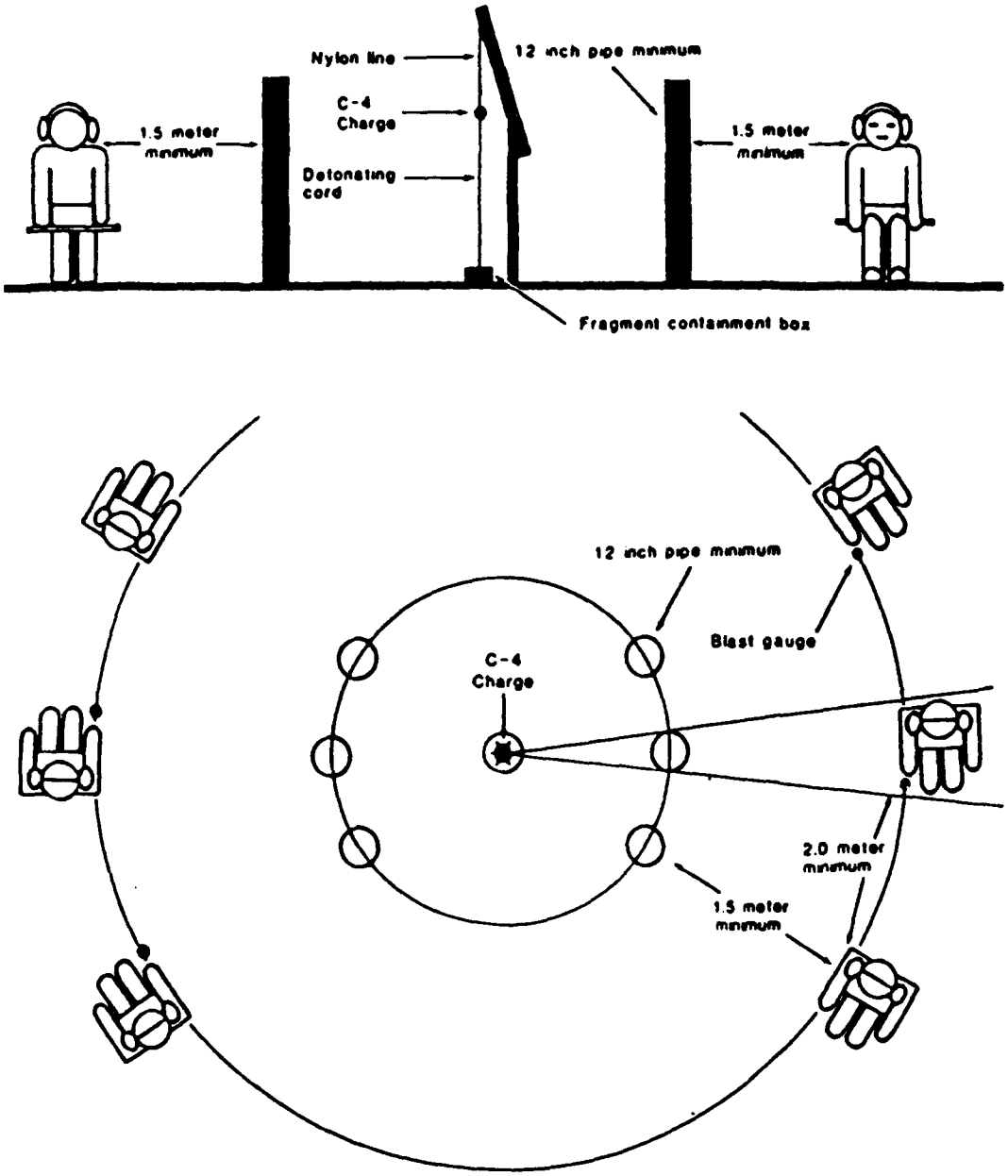


Figure II-1. Diagram of typical subject positioning re: blast source. Between each subject and the explosive is a metal pipe to serve as a debris shield.

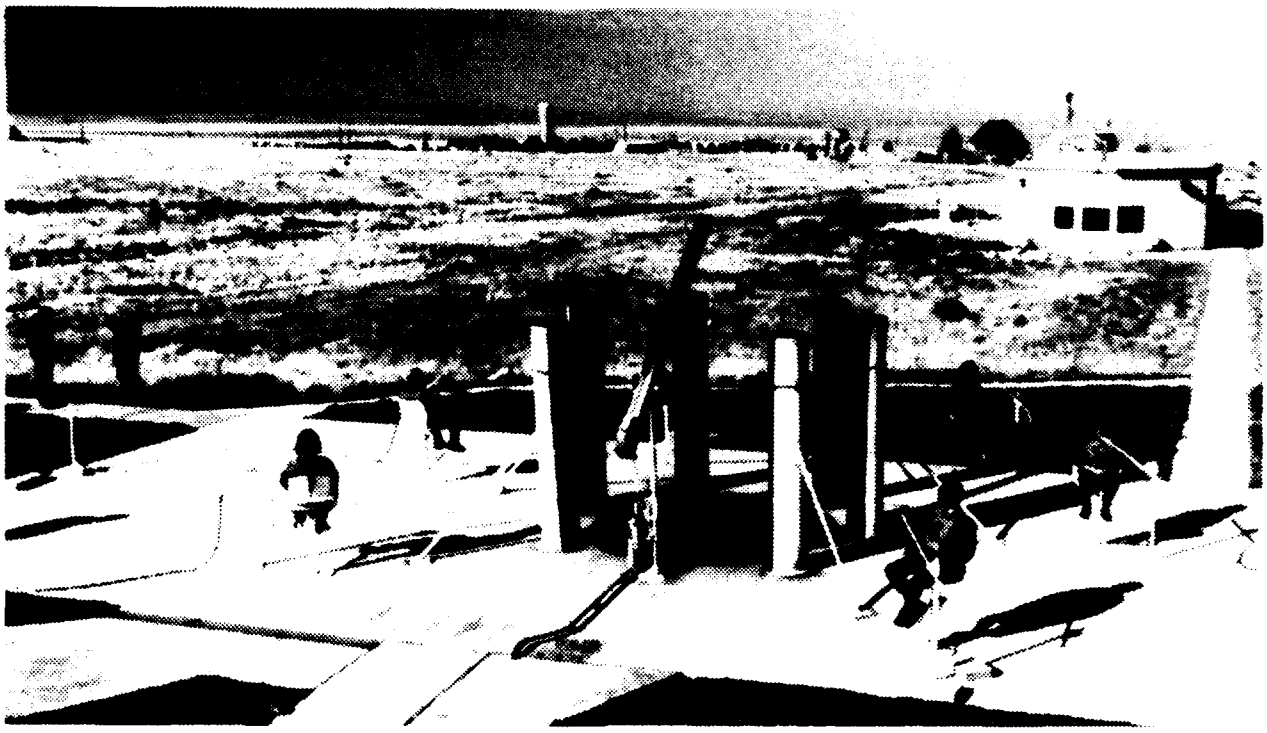


Figure II-2. 5-meter Setup.

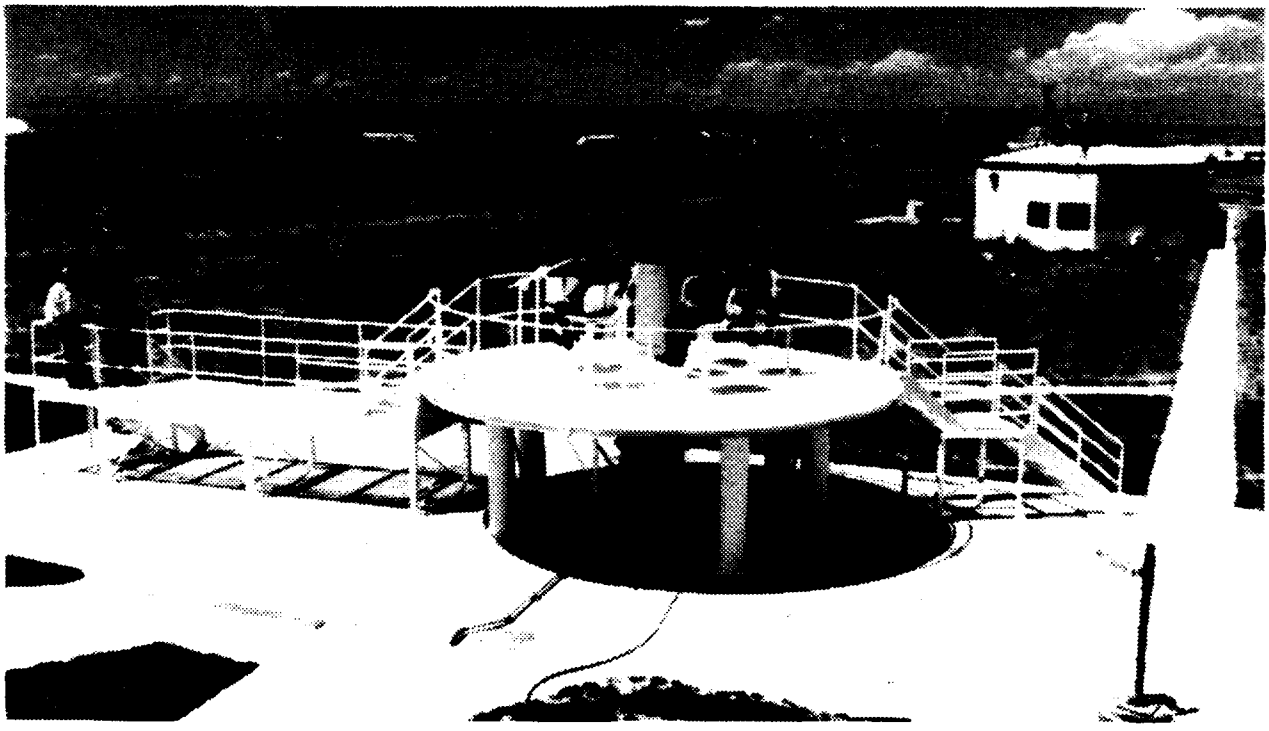


Figure II-3. 1-meter Setup

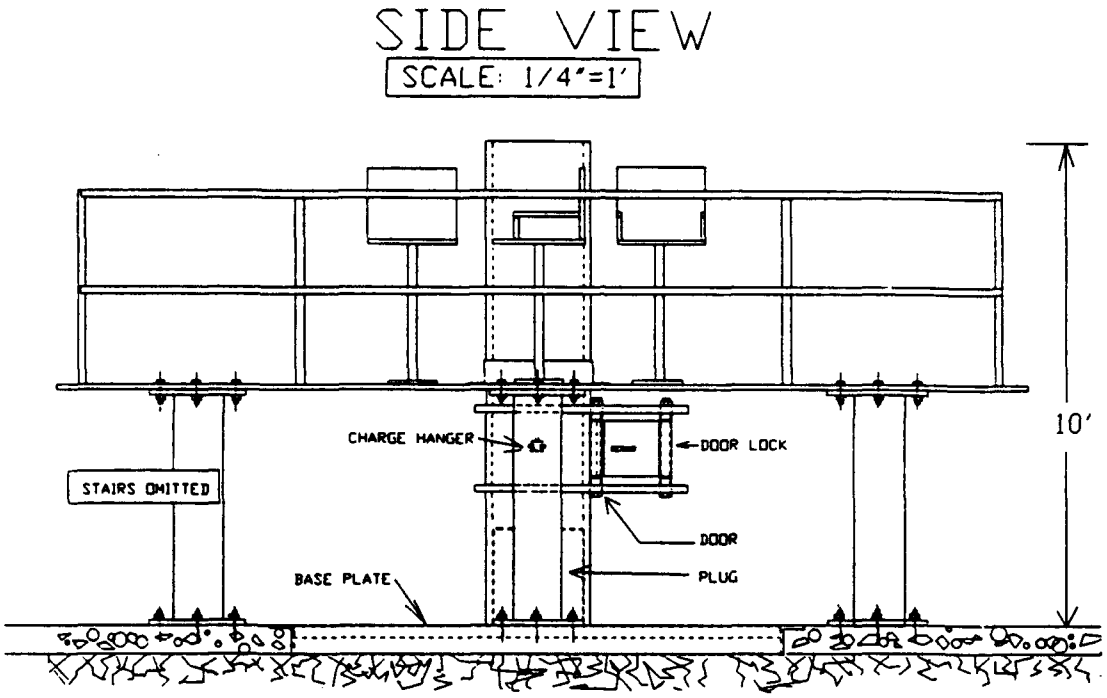


Figure II-4A. The Mortar System.

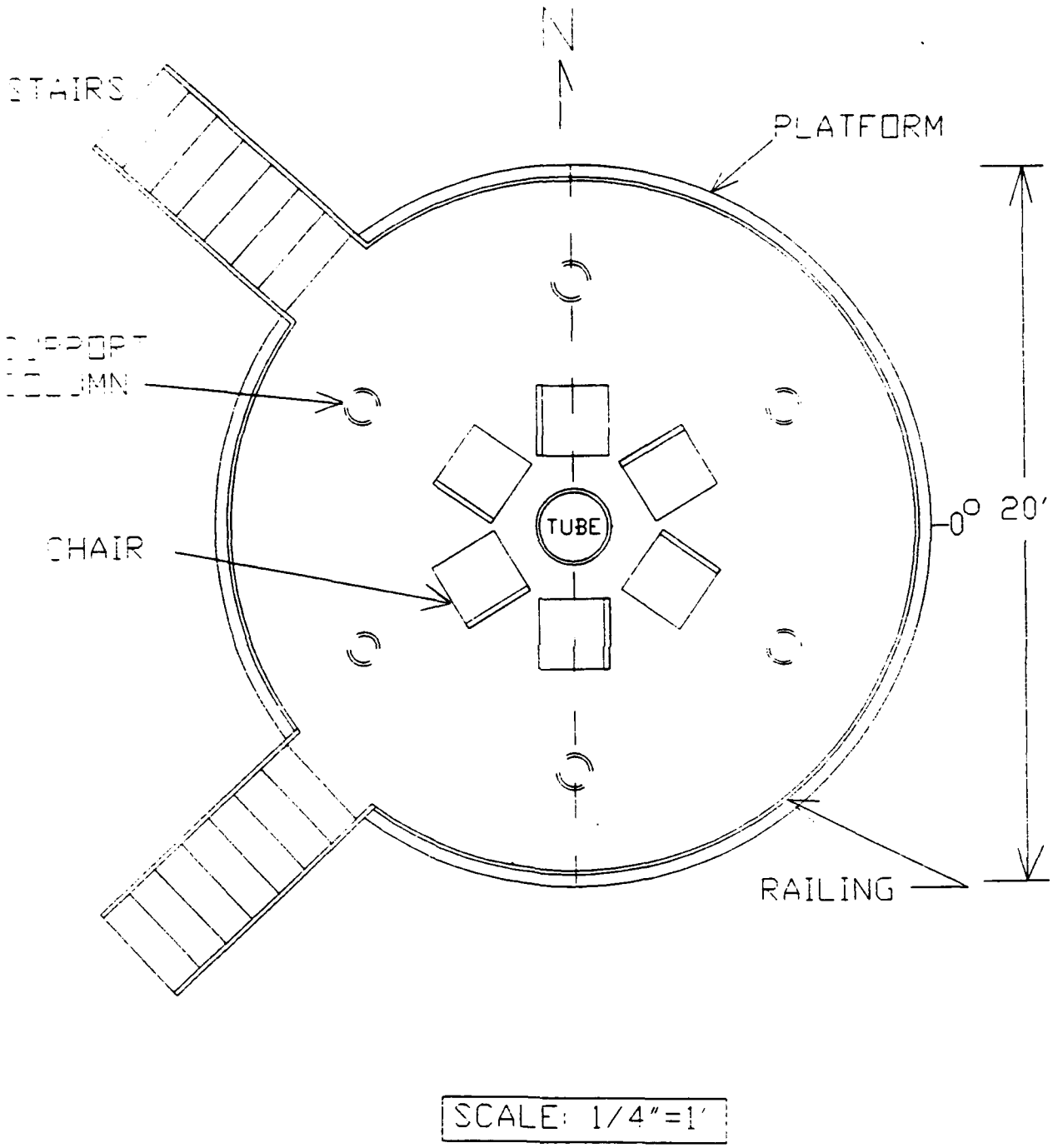


Figure II-4B. The Mortar System (Top View)

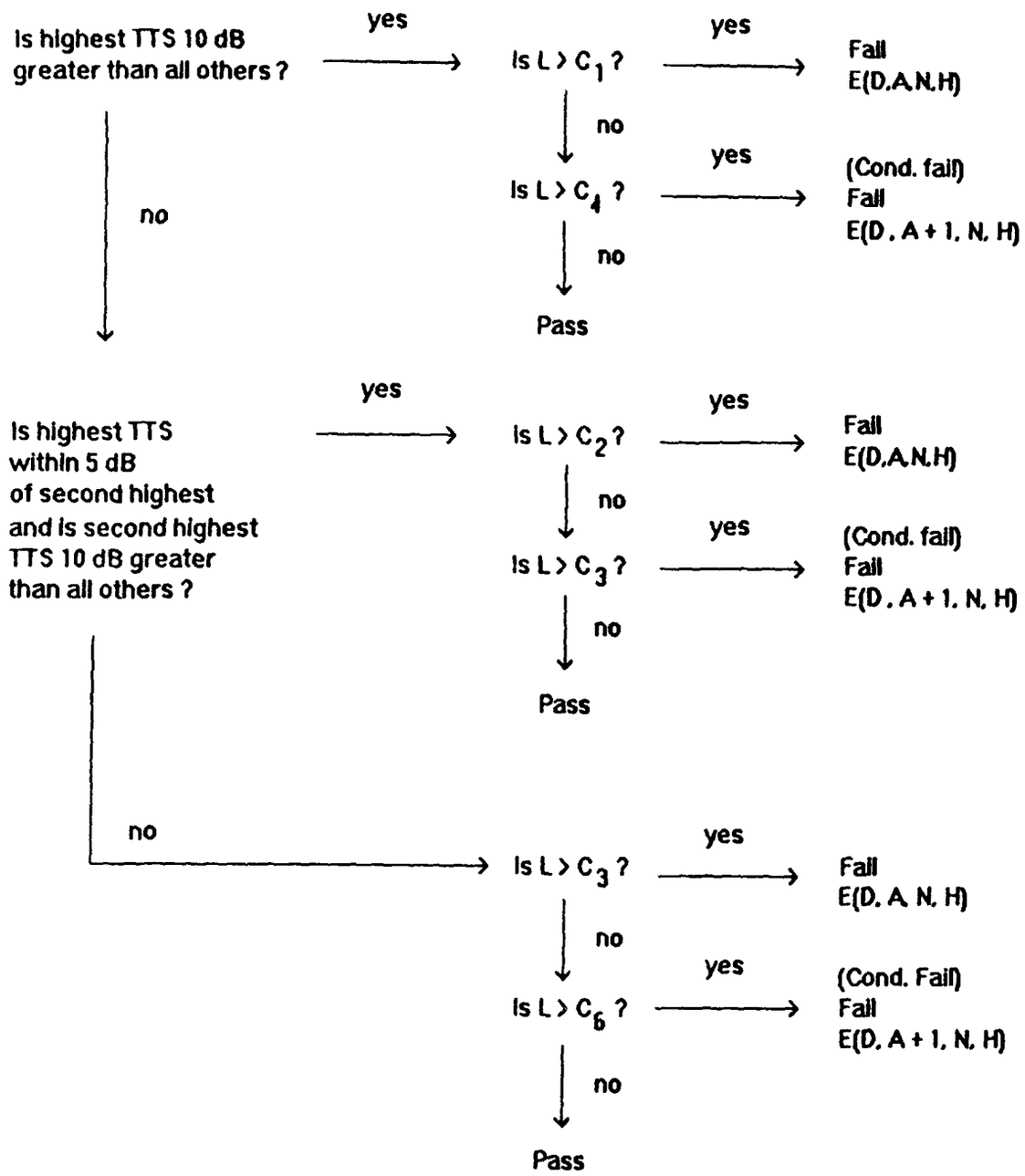


Figure II-5. Decision tree for critical TTS pass-fail decision.

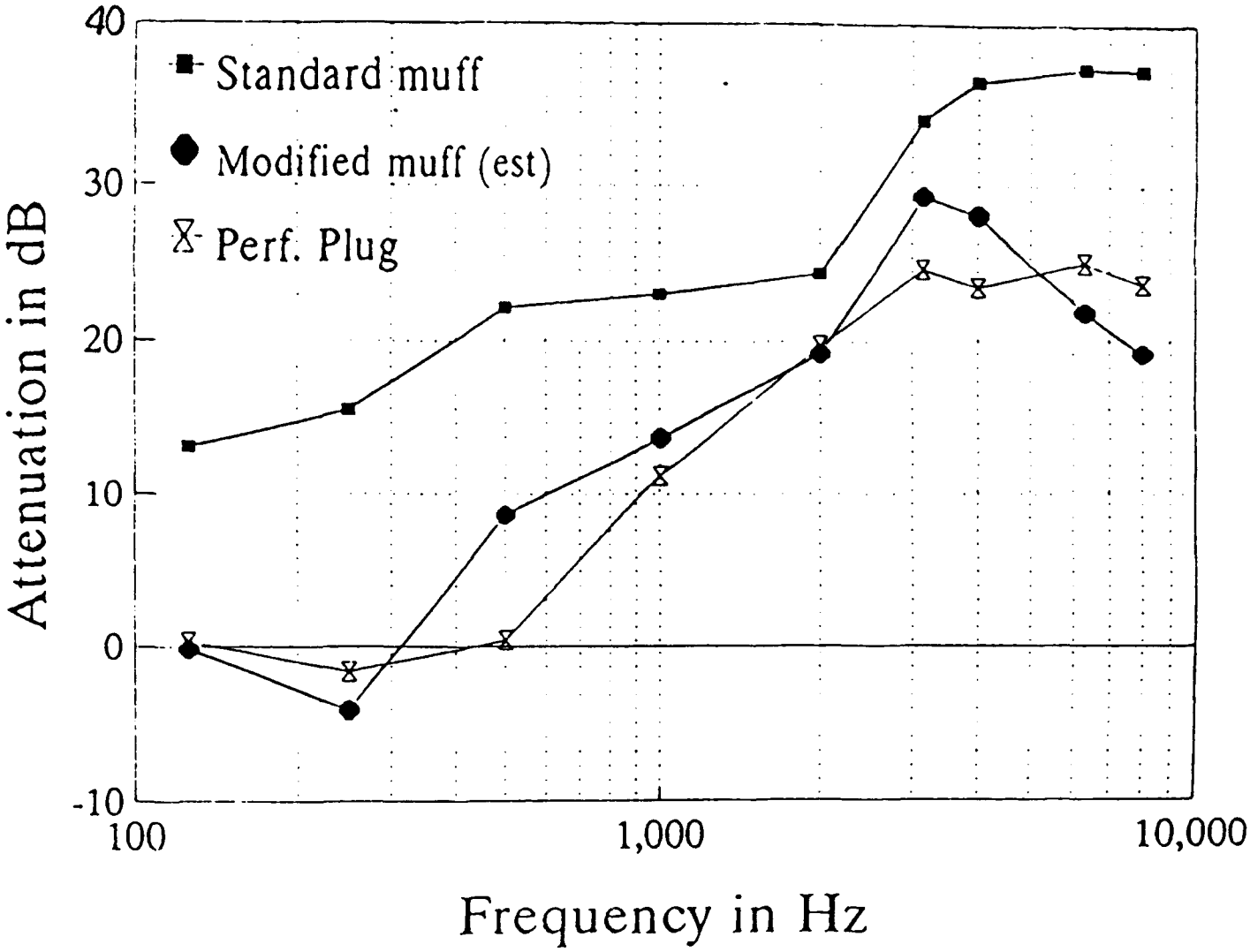


Figure II-6. Comparison of the Real Ear Attenuation for the Standard RACAL® muff modified by eight tubes through the seal which simulated leaks and a special plug perforated with a hole through the plug so that sound could reach the tympanic membrane unimpeded.

III. RESULTS

A. OVERVIEW OF ALL TESTS

1. 5-m Distance, Study Conditions "B" and "M"

a. Testing started with the 5-m distance in October 1989. Bare charges of C-4 explosive were used at a 5-m distance from the subjects. This resulted in peak sound pressure levels ranging from 173 dB at Level 1 to a maximum of 191 dB at Level 7. The A-duration of these exposures was approximately 3 msec. This was called study distance "B." The RACAL® muff (see Figure III-1) was used as the hearing protector under test. A total of 62 subjects started and 41 subjects finished the test sequence.

b. The RACAL® muff protected the subjects so well that virtually no TTS occurred. For this reason, the RACAL® muff was modified by putting eight tubes through the seal. The 5-m distance was reused. This exposure condition was called study distance "M" and lasted from August 1990 to June 1991. A total of 59 subjects started and 57 subjects finished the study sequence.

2. 1-m Distance, Study Condition "D"

The 1-m distance (Study Condition D) used a 22-inch-I.D., 26-inch O.D. with a 2-inch-thick wall steel tube, mortar simulator (see Figure II-3). The resulting peak SPL ranged from 175 dB (Level 1) to 196 dB (Level 7). The A-duration was approximately 0.8 msec. The modified muff was again used. A total of 65 subjects started and 49 subjects finished the study. The testing started in July 1991 and was finished in May 1992.

3. 3-m Distance, Study Condition "C"

The next study distance (study condition C) was the 3-m distance. The same setup as the 1-m distance was used, except that the distance from the lip of the tube was increased in order to increase the A-duration. The peak SPL varied from 173 dB at Level 1 to 193 dB at Level 7. The A-duration was approximately 1.5 msec. A total of 68 subjects started the study and 56 subjects finished. The testing started on June 1992 and finished in April 1993.

4. 3-m Distance, No-Countdown Study

An additional study (no-countdown) was piggybacked onto the main 3-m study starting in January 1993. This study eliminated the countdown normally given the subjects before each shot. Only the 22 subjects that finished the 3-m distance after 1 January 1993 were eligible to volunteer for this study. Levels 1 to 7 were repeated using only six shots each. A total of 20 subjects started

and 4 subjects finished the study. The testing started in January 1993 and finished in April 1993.

5. 3-m Distance - Perforated Ear Plug Study Condition "P"

The final study (condition "P") was a repeat of the 3-m distance using a perforated ear plug (see Figure III-2). Because of the time available, only 19 subjects entered this study. Numerous auditory failures of the perforated plug occurred and many of the matrix conditions were closed out. Six subjects finished the perforated plug part of the study early. Seven subjects were finished early enough to start the second-level hearing protection (E.A.R.® foam plugs) part of the study. Of these seven, only one completed the study. The perforated ear plug study (condition "P") was started in May 1993 and was finished in August 1993.

Table III-1

Total Number of Test Subjects

Study Condition	Subjects Started Final Test	Subjects who completed total test sequence	Subjects who quit before end of study	Subjects whose exposure was stopped at discretion of PI or Med. Monitor	Subjects who were administratively stopped (disciplinary)
5 meter (B)	62	41	16	4	1
5 meter (M)	59	57	1	0	1
1 meter (D)	65	49	9	7	0
3 meter (C)	68	56	9	0	3
3 meter (P)	19	6	12	1	0

B. ATTENUATION OF HEARING PROTECTORS USED

1. RACAL® Muff

The attenuation baseline from the Physical Ear Attenuation Tests (PEAT) of the RACAL® muff are shown in Table III-2. The baseline was established by using the mean of at least eight tests. These tests were screened for obvious mistakes, fitting problems, or tests that were not consistent with the majority of the tests. The mean data are from 69 subjects. The average standard deviations are the average from these subjects. The standard deviation of the mean is calculated from the mean baseline values of each subject.

TABLE III-2

Attenuation of the RACAL® muff from the PEAT Tests (69 Subjects)

Frequency, Hz	Left Ear		Right Ear	
	Mean, dB	Standard Deviation	Mean, dB	Standard Deviation
125	8.0	1.6	8.8	1.9
160	12.8	1.4	12.6	1.3
200	14.0	1.6	14.7	1.2
250	15.6	1.6	16.1	1.3
315	15.8	1.9	16.9	1.2
400	22.1	1.7	21.8	1.5
500	28.6	1.7	28.5	1.2
630	29.6	2.9	30.1	1.9
800	32.0	2.5	31.6	1.8
1000	32.3	2.1	32.1	1.2
1250	31.7	2.1	30.2	1.7
1600	32.5	1.9	31.9	1.4
2000	30.9	1.7	31.4	1.9
2500	29.4	3.0	29.7	1.8
3150	33.3	2.8	32.5	1.7
4000	32.8	3.1	31.4	1.9
5000	23.3	4.1	22.9	2.9
6300	19.4	2.8	17.2	2.5
8000	14.4	2.4	12.4	1.9
10000	10.5	2.4	9.3	1.7

2. RACAL® Modified Muff

Similar to the unmodified RACAL® muff, mean baseline values were developed for each subject until November 1990. At this time, the PEAT tests were dropped from the protocol because the purpose of the tests, subject safety, was not valid in that the blast waves were moving the muffs to a different position. The baseline values included the results from 57 subjects and are summarized in Table III-3.

Table III-3

Mean Attenuation Values for the Modified RACAL® Muff (Right ear modified) using the PEAT baseline values for 57 subjects.

Frequency, Hz	Left Ear		Right Ear	
	Mean, dB	S.D.	Mean, dB	S.D.
125	9.4	2.6	-2.7	2.6
160	12.3	2.8	-3.7	3.2
200	13.0	3.0	-5.0	3.6
250	16.0	2.3	-4.1	3.7
315	17.6	2.9	-0.2	3.3
400	23.1	2.7	4.6	2.6
500	29.6	2.9	10.3	3.8
630	32.5	3.2	13.9	3.5
800	33.5	3.6	17.0	2.2
1000	34.5	3.4	20.1	2.1
1250	32.6	3.4	22.0	1.7
1600	33.8	3.9	25.6	1.6
2000	31.0	3.0	28.6	2.0
2500	32.2	4.1	31.1	2.5
3150	36.9	4.9	33.5	2.7
4000	39.4	6.7	33.4	3.6
5000	32.5	9.8	27.8	6.0
6300	31.0	11.2	22.1	6.7
8000	28.4	12.5	18.1	7.1
10000	25.7	12.7	20.4	9.6

3. E.A.R.® Foam Plug

The attenuation baseline values are from Real Ear Attenuation Tests (REAT). A summary of the baselines from 69 subjects is shown in Table III-4. Because of the low amount of TTS and, thus, the lack of use of second-level hearing protection, baselines were not made after April 1990 unless they were needed.

TABLE III-4

Mean Baseline Attenuation Values for the E.A.R.® Foam Plug.

Group P, Left Ear, 19 Subjects										
	2K	4K	3K	6K	8K	2K	1K	500 Hz	250 Hz	125Hz
Sum	736	855	902	836	879	746	597	583	574	538
Ave.	39	45	47	44	46	39	31	31	30	28
Std. Dev.	4.1	3.5	4.4	3.5	6.6	4.1	3.5	3.7	4.8	5.1
Group B, Left Ear, 69 Subjects										
	2K	4K	3K	6K	8K	2K	1K	500 Hz	250 Hz	125Hz
Sum.	2898	3209	3367	3115	3224	2922	2520	2494	2533	2264
Ave.	42	47	49	45	47	42	37	36	37	33
Std. Dev.	4.1	4.3	4.8	4.3	8.7	3.8	5.3	5.8	6.1	5.7
Group B, Right Ear, 69 Subjects										
	2K	4K	3K	6K	8K	2K	1K	500 Hz	250 Hz	125Hz
Sum.	2752	3189	3392	3126	3283	2866	2517	2506	2418	2184
Ave.	40	46	49	45	48	42	36	36	35	32
Std. Dev.	4.2	4.5	4.8	4.6	8.1	3.8	5.6	6.3	6.3	6.1

Note: The frequencies listed are in the order that they were given to the subjects. Note that 2K was given twice.

4. Perforated Plug

The attenuation baselines are from the REAT of 19 subjects. The mean attenuation is shown in Table III-5.

Table III-5

Mean Baseline Attenuation Values for the Perforated Plug

DISTANCE P -- RIGHT EAR ONLY										
SUBJECT	2000	4000	6000	3000	8000	2000	1000	500	250	125
PAA1	25	24	32	30	21	26	15	6	3	5
PAA3	26	25	35	27	45	29	21	20	13	12
PAA4	30	23	37	34	39	32	21	6	0	3
PAA5	16	17	17	23	24	15	9	2	-5	-3
PAA6	29	29	35	33	31	30	19	13	7	5
PAA7	27	25	36	29	33	31	18	8	2	6
PAB1	27	31	28	31	41	30	22	13	5	9
PAB2	32	27	29	30	26	31	19	12	7	5
PAB3	25	26	28	29	31	23	14	3	2	4
PAB4	26	26	26	28	25	28	17	3	3	6
PAB5	23	20	27	25	19	28	12	3	-4	0
PAB6	20	19	36	23	26	21	14	5	5	4
PBC1	23	24	19	22	26	22	9	3	2	3
PBC2	25	23	29	23	27	27	16	9	-1	-2
PBC3	26	30	33	31	30	25	17	12	7	4
PBC4	25	19	20	20	21	24	16	11	2	4
PBD1	24	27	29	31	26	23	14	9	4	4
PBD2	25	22	25	27	29	25	12	1	0	-1
PBD3	26	22	29	21	29	27	13	12	3	1
SUM	480	459	550	517	549	497	298	151	55	69
AVERAG	25	24	29	27	29	26	16	8	3	4
STD DEV	3.461568	3.819004	5.844976	4.223992	6.806	4.232981	3.801354	5.02741	4.135144	3.608794
COUNT	19	19	19	19	19	19	19	19	19	19

C. AUDITORY

1. 5-m Distance, Unmodified Muff, Study Condition "B"

a. Summary of Auditory Failures

For the 62 subjects that started the study, there were no auditory failures and only one tentative conditional failure that was cleared by the subject's passing a condition of the same level with more shots. The summary of these conditional failures is as follows:

TABLE III-6

Summary of Conditional Failures
5-m Distance

Subject	Condition	TTS_2	TTS_{max}	Frequency	Cleared
BDE5	6/6	16	16 (2 min)	8 kHz	Yes

b. Matrix Status

Because of the lack of auditory failures, the final matrix, Figure III-3, is quite simple. Basically, there were no auditory failures nor full failures against any of the cells of the matrix.

c. Mean TTS vs Exposure Condition

While there may not be 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. For this study distance, this approach is fully valid since none of the subjects were dropped because of auditory failure. (The nature of the Walk-Up Study makes a normal regression analysis questionable because the more sensitive individuals are selected out before the high-exposure levels.)

Typical results of the linear regression of TTS vs Level for 6 shots is shown in Figure III-4. The frequency of 4000 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 are given in Table III-7.

TABLE III-7

Slope of a Linear Regression vs. Intensity Level for Various Study Distances

Exposure Condition		Frequency, kHz					
		1	2	3	4	6	8
5-m "B"	Right	-.1	-.05	-.11	-.03	-.06	-.03
	Left	-.17	-.03	-.07	+.05	-.08	.01
5-m "M"	Right	.01	.01	.12	.04	.17	.05
	Left	-.18	.01	-.04	.03	.06	-.12
1-m "D"	Right	.02	.09	.08	.11	.17	.04
	Left	.08	-.12	.05	-.06	-.02	-.02
3-m "C"	Right	-.25	.09	.12	.39	.38	.48
	Left	-.06	.04	-.06	.02	.08	.02
3-m "P	Right	-.14	.62	.56	.05	.69	.94
	Left	.06	.26	-.07	.06	.31	.25

For the amount of decibel increase in TTS_2 vs. a decibel increase in peak level, divide values by 3. Thus, a 1 dB increase in peak level should cause approximately a 0.31-dB increase in mean TTS at 8 kHz for six shots at the 3-m distance while wearing the perforated plug (0.94 ÷ 3 = 0.31).

2. 5-m Distance, Modified Muff, Study Condition "M"

a. Summary of Auditory Failures

Of the 59 subjects that started the study, 57 completed the study. There were four subjects with conditional failures, two of which were cleared. One subject had five conditional failures, of which only the first one was cleared. A summary of these failures is as follows:

Table III-8

Conditional Failures, 5-m Distance
Modified Muff

Subject	Condition	TTS_2	TTS_{max}	Frequency	Cleared
MAA4	6/50	21	21	8 K	Yes
MAA5	6/100	18	27 (20 min)	4 K	No
MEH1	6/12	20	20 (1 hr)	8 K	Yes
MEI5	5/6	21	21	4 K	Yes
MEI5	6/6	23 25	23 25 (20 min)	3 K 8 K	No No
MEI5	4/25	17	17	250 Hz	No
MEI5	3/50	19	19	8 K	No
MEI5	2/100	27	27	2 K	No

The TTS of Subject MAA5 did grow as shown in Figure III-5.

There was one subject with a full auditory failure. This subject failed after condition 6/100. The principal investigator then stopped further exposure because of the amount of the TTS. Figure III-4 also shows the recovery of this TTS.

TABLE III-9

Full Audiometric Failures, 5-m Distance
Modified Muff

Subject	Condition	TTS_2	TTS_{MAX}	Frequency	24 Hr Recovery	Allowed to Continue
MAA2	6/100	42 59	53 59	6 K 8 K	Yes Yes	No

b. Matrix Status

The matrix of failures is shown in Figure III-6. With only one auditory failure (MAA2) and one conditional failure (MEI5) impacting on any condition, the results indicate that all exposure conditions except perhaps 6/100 should be safe. Subject MAA5 also is considered to have impacted on condition 6/100 because of the TTS growth at 20 minutes and because TTS_{max} was more than 25 dB. Subject MFJ5 also impacted the matrix condition because of a non-auditory failure.

c. Mean TTS vs Exposure Condition

As with distance B, a regression analysis was performed to see if there was any increase of TTS with an increase of SPL or with exposure energy. Because the only auditory failure was at condition 6/100, the early termination of a more sensitive subject will not be a problem. A typical fit between TTS and level is presented in Figure III-7. This is again the case in which the slope was the greatest. Table III-7 summarizes the slopes of the remaining frequencies.

3. 1-m Distance, Modified Muff "D"

a. Summary of Audiometric Failures

Of the 65 subjects who entered the study, 49 completed the study. There were 27 incidents of conditional failures with 16 subjects involved. There were four incidents of full audiometric failures with three separate subjects involved. The summary of these failures is:

Table III-10

1-M Distance, Conditional Failures
Modified Muff

Subject	Condition	TTS_2	TTS_{MAX}	Frequency	Cleared
DAA1	6/100	18	18	6 K	No
DAA5	4/100	20	20	2 K	No
DBC2	6/50	18	18	8 K	No
DBC2	5/100	15	15 (20 min)	8 K	No
DBC4	5/12	18	18	4 K	No
DBC4	4/25	24	24	8 K	No
DBC4	3/50	22	22	1 K	No

DBC4	2/100	19	19	1 K	No
DBC4*	6/50	21	21	6 K	No
DBC4*	5/100	18 11	18 (1 hr) 19 (1 hr)	6 K 8 K	No
DBD1	6/25	16	21 (20 min)	2 K	Yes
DBD1	6/100	16	16	2 K	No
DCE4	6/100	21	22	2 K 8 K	No
DCE5	1/6	19	19	250 Hz	Yes
DCE5	6/50	17 15	17 16	250 Hz 500 Hz	No
DCF3	6/50	13 13 (min)	13	2 K	No
DCF5	6/25	22	22	8 K	No
DEI1	6/25	19	19	6 K	No*
DEJ3	6/25	17	17	2 K	No
DEJ5	5/7	18	18	4 K	No
DEJ5	2/25	15	15	4 K	Yes
DEJ6	5/100	16	16	8 K	No
DFK5	2/6	20	20	8 K	No
DFK5*	6/25	16	16	8 K	No
DFL1	6/12	15	18 (1 hr)	1 K	Yes
DFL3	6/6	4	19 (1 hr)	4 K	Yes
DFL4	6/12	15	15	3K	Yes

* Second-level hearing protection.

From the above list, 6 of the 27 conditional failures were cleared by the subject passing a more energetic condition.

There were 17 full audiometric failures that occurred. This occurred in 13 subjects as several subjects had more than one failure as they progressed through the matrix. These failures were:

Table III-11

1-m Distance, Audiometric Failures
Modified Muff

Subject	Condi-tion	TTS_2	TTS_{max}	Fre-quency	24 hr Re-covery	Clear to Con-tinue
DAA4	6/25	11 20	48 (2 HR) 40	3 K 4 K	Yes	No
DAA5	5/6	35	35	4 K	Yes	Yes
DAB1	6/100	31	31	6 K	Yes	Yes
DAB1	5/100	33 45	33 45	3 K 4 K	Yes	Yes
DBC4	7/6	29		8 K	Yes	Yes
DBD6	6/12	22	22	3 K	Yes	Yes
DCE5	5/100	34	41 (1 hr)	3K	Yes	No
DCF5	5/50	31	31	8 K	Yes	Yes
DCF3	5/100	29 57 52 27	29 (20 min) 57 (20 min) 52 30 (20 min)	1 K 2 K 3 K 4 K	No	No
DEI7	6/12	30	30	6 K	Yes	Yes
DEI7	5/50	47	47	8 K	Yes	Yes
DEJ5	7/6	2 14	28 (20 min) 14	3 K 6 K	Yes	Yes
DEJ5	4/12	37	37	4 K	Yes	Yes
DEJ3	5/50	27 33	27 33	2 K 3 K	No	No
DFK5	2/12	28	28	6 K	Yes	Yes
DFK5*	6/50	27	27	8 K	Yes	Yes
DFK3	5/50	50	50	4 K	No	No

* Second-level hearing protection.

Of the 13 subjects, five of them had failures of such a nature that the PI determined that their exposures should stop. For three of these 5 subjects, the reason was a recovery time of more than 24 hr. However, all three subjects recovered within 48 hr.

There were two subjects that showed a TTS growth. In one subject, this lasted up to 2 hr before recovery started. Figure III-8 depicts the growth and recovery of TTS in this subject. Subject DEJ5 showed a strong growth of TTS between 2 and 20 min, then a relative normal recovery (see Figure III-9).

Subject DCF3 had a considerable amount of TTS. However, as seen in Figure III-10, this TTS recovered normally.

b. Matrix Status

The status of the final matrix of failures is shown in Figure III-11. Sixty-five subjects entered the mortar distance study. Of these subjects, 18 of them had one or more failures. Two of the cells (6/100 and 5/100) of the matrix were closed out with 11 or more unconditional failures. A summary of the subjects (by subject number) who were counted as a failure against each cell of the matrix is provided in Figure III-12.

c. Mean TTS vs Exposure Condition

For this study distance, the problem of eliminating the sensitive subjects from the more energetic exposure conditions will certainly reduce the amount of TTS predicted by any regression analysis. Figure III-13 shows the regression using the frequency with the greatest slope. This was 6 kHz. Note the very small coefficient of correlation (R). To be significant at the ±5% level, the coefficient of correlation should be above 0.25. In this case, it was 0.074. Again, refer to Table III-7 for all the slopes.

4. 3-m Distance, Modified Muff, Study Condition "C"

a. Summary of Audiometric Failures

For the 68 subjects who entered the study, 43 finished the study. There were 19 conditional failures by 14 subjects. Seven of these conditional failures were cleared. There were 11 full failures involving 10 subjects. The summary of the conditional failures follows:

Table III-12

Conditional Failures, 3-m Distance
Modified Muff

Subject	Condition	TTS_2	TTS_{max}	Frequency	Cleared
CAA4	5/6	23	23	8 K	No
CAA4	5/12	18	20 (20 min)	8 K	Partially
CAA6	5/50	17	18 (1 hr)	8 K	No
CAA6	4/50	10 13 1	19 (3 hr) 18 (3 hr) 16 (1 hr)	2 K 6 K 8 K	No No
CBC5	6/12	20		3 K	Yes
CBC6	3/6	19		6 K	Yes
CCE3	4/6	9	17 (20 min)	8 K	No
CCE3	4/12	9	16 (1 hr)	8 K	No
CCE3	3/25	5	21 (1 hr)	8 K	No
CDG3	4/6	23		8 K	Yes
CEH2	5/6	22 14	22 21 (20 min)	4 K 6 K	Yes Yes
CEH2	6/25 (6/9)	N/A	13 (18 min)	2 K	No
CEI4	6/25	16	16	8 K	Yes
CFJ6	6/25	17		2 K	No
CFK3	7/6	18		8 K	No
CGK1	5/6	17		3 K	Yes
CGL4	4/6	20 22		3 K 4 K	Yes
CFK1	5/6	17		3 K	No
CGL3	7/6	21		8 K	No

A summary of the full audiometric failures follows:

Table III-13

Full Failures, 3-m Distance
Modified Muff

Subject	Condition	TTS_2	TTS_{max}	Frequency	24-Hr Recovery	Allowed to Continue
CAA6	6/12	25		3 K	Yes	Yes
CAA3	6/50	54		6 K	No	No
CAB5	6/25	36		8 K	Yes	Yes
CBC4	6/50	44 34		3 K 4 K	No	No
CBC3	6/100	45		8 K	No	No
CBC5	6/100	26	42 (20 min)	4 K	Yes	No
CCE1	6/6	20 30	27 31 (20 min)	6 K 8 K	Yes	Yes
CCE1	5/50	28		3 K	Yes	Yes
CFJ5	6/6	49		8 K	Yes	Yes
CFJ7	6/25	25	43 (1 hr)	4 K	Yes	No
CFK2	5/6	21	27 (20 mi	4 K	Yes	Yes

Of the 11 failures, 3 showed a recovery that took more than 24 hr. Two more subjects had a growing TTS that exceeded 40 dB. In all, 5 of the 10 subjects' exposures were terminated early at the discretion of the principal investigator or in accordance with the protocol.

b. Matrix Status

The final status of the numbers of failures per matrix condition is shown by Figure III-14. A summary of subjects who counted as failures against each condition is provided in Figure III-15.

c. Mean TTS vs Exposure Condition

As with the previous distance, the problem of eliminating the more sensitive subjects must be addressed. By the time condition 6/100 is reached, just a little more than 50% of the

subjects that started remained. Therefore, the regressions that were run will underestimate the amount of TTS occurring. These regressions will indicate, however, any systematic change of TTS with level for the subjects with the more resistant ears. With this caveat in mind, a regression of TTS vs SPL is presented in Figures III-16 (4000 Hz) and III-17 (8000 Hz). The coefficient of correlation for both frequencies was 0.1, far from significant.

5. No-Countdown, 3-m Distance, Modified Muff

a. General

The no-countdown study was accomplished using volunteers who had completed and passed the study matrix for the 3-m distance. It was started in January 1993 and subjects from groups CEH, CEI, CFJ, CFK, CGL, and CGM were involved. Twenty subjects volunteered to participate. Of these 20 subjects, only four completed condition 7/6 (the study's ending point). There was one conditional failure:

Table III-14

Conditional Failure
No-Countdown Study, 3-m Distance

Subject	Condition	TTS_2	TTS_{max}	Frequency	Cleared
CGL5	3/6	16	16	3 K	N/A*

* For this study, a conditional failure stopped further exposure.

b. TTS Comparisons

Except for the one conditional failure after Level 3, there were no TTS failures. A comparison of mean difference between the post 2-minute audiograms from the 6-shot countdown series vs the 6-shot no-countdown series for the same subjects is shown in Table III-15. While it appears there might be a slight increase in TTS at 4 and 6 kHz from the no-count[illegible] the effect is not robust and seems to decline at higher expo[illegible] els. Of course, at the higher levels the more sensitive subje[illegible] may have dropped out of the study. We conclude that the lack of a countdown is unlikely to be of practical significance with respect to TTS.

TABLE III-15

Mean Audiometric Difference Between Countdown and No-Countdown Exposures, Post 2-Minute Audiograms

Level	Frequency, Hz						
	500	1000	2000	3000	4000	6000	8000
1	-1.2	0.4	0.8	1.2	1.1	2.0	2.2
2	2.0	1.0	-0.3	0.9	-2.3	0.4	-0.6
3	1.1	-0.7	1.8	2.7	3.2	3.8*	1.1
4	1.5	-0.8	2.7	1.7	1.6	3.4	1.4
5	0.3	-1.1	1.7	-0.1	3.9*	-0.3	0
6	1.9	0.5	-1.0	1.1	2.2	-1.1	-2.8
7	-0.8	-2.4	0.8	1.4	1.2	-1.0	-1.6

* Significant at the P = <0.05 level.
Note: Positive levels would show more TTS from No-Countdown Condition.

6. 3-m Distance, Perforated Plugs, Study Condition "P"

a. This study started May 1993 and included only four groups: PAA, PAB, PBC and PBD. Of the 19 subjects that started the study, eight subjects had conditional failures. There were 11 conditional failures overall. There were 13 full audiometric failures involving 10 subjects. Second-level hearing protection (E.A.R.® foam) was also used for seven subjects. There was one conditional failure with second-level hearing protection. The conditional failures were:

Table III-16

Conditional Failures, 3-m Distance, Perforated Plugs

Subject	Condition	TTS_2	TTS_{max}	Frequency	Cleared
PAA7*	3/12	20		2 K	No
PAB2*	6/6	17		8 K	No
PAB2*	4/50	18		3 K	No
PAB3*	1/6	20		4 K	No
PAB4*	2/6	17		4 K	Yes

PAB4*	3/33	20		4 K	No
PAB5*	3/25	1	17 (20 min)	2 K	No
PAB6*	2/6	17		5 K	Yes
PBC1*	3/6	20		8 K	No
PBC1*	2/12	20		8 K	No
PBC3*	2/50	21		500 Hz	No
PBC4**	7/6	21		8 K	No

* First-level hearing protection
** Second-level hearing protection

A summary of the full audiometric failures for Level 1 protection follows:

Table III-17

Full-Audiometric Failures, 3-m Distance, Perforated Plugs

Subject	Condition	TTS_1	TTS_{max}	Frequency	24 Hr Recovery	Allowed to Continue
PAA1	3/6	32		6 K	No	Yes
PAA6	4/6	40		8 K	Yes	Yes
PAA7	5/6	27		3 K	Yes	Yes
PAA4	5/25	30		4 K	Yes	Yes
PAA4	4/25	46		2 K	Yes	Yes
PAB2	6/12	33		4 K	Yes	Yes
PAB4	6/12	50		4 K	Yes	Yes
PAB4	5/25	32		4 K	Yes	Yes
PAB6	4/12	17	31 (7 hr)	2 K	No	No
PBC1	1/25	27		8 K	Yes	Yes
PBD3	4/6	28	21 (20 min)	2 K 3 K	Yes	Yes
PBD3	2/12	31 17		2 K 3 K	No	No
PBD2	2/50	25		4 K	Yes	Yes

Of the 10 subjects who failed, four of them were stopped from further exposure. Three of these four were stopped because of lack of full recovery within 24 hr and one (subject PAA4) was stopped due to an apparent increasing sensitivity to the noise exposure.

b. Status of the Matrix

The matrix is shown in Figure III-18. Even though only 19 subjects started, much of the matrix was closed off by excessive failures. Because of the known lack of 60 subjects (the plan was to start only 24 subjects) the number of failures required to close a cell was set at 7. When it was known that only 19 would actually start, this number was set at 6. Note that before the end of the study, all conditions as energetic or more energetic than 4/6 and 3/50 were closed. Figure III-19 summarizes each matrix cell and provides the subject number for each subject that counts as a failure against that cell. The number of subjects that passed each cell is also included. For instance, for condition 2/100, there were five failures against the cell while only two subjects passed the 2/100 exposure.

c. TTS Comparisons

Because of the few subjects that passed Level 4, a regression of TTS vs level was only done on the first four SPL's. A typical example is shown in Figure III-20. As would be expected from the status of the matrix, there was considerably more effect of level on TTS. The highest coefficient of correlation was at 3 kHz. It was 0.3, which is still less than the 0.45 required for 19 subjects for ± 5% significance.

D. NON-AUDITORY AND OTHER

1. 5-m Distance, Unmodified Muff

a. Non-Auditory Injury

Of the 62 subjects that started the study, there was only one subject with a non-auditory injury. These were:

Table III-18

Non-Auditory Injury
5-m Distance, Unmodified Muff

Subject	Condition	Non-Auditory Injury	Recovery Time
BBB6	5/6	Petechiae in Larynx	<5 days

This was the only case of petechiae on the larynx-pharynx discovered even though otolaryngoscopic examinations were given at Levels 6/6, 7/6, and 6/12 through Group E and at 7/6 for Groups F,

G, and H. Likewise, the stool guaiacs (given after 6/25 up to Group F and after 7/6 for Groups G and H were all negative.

The greatest problem encountered with the exposures was with the group BEG in March 1990. At Level 7, several of the subjects had a reddening of the upper right arm (side closest to the blast). Figure III-21 shows this reddening. This reddening was found to be from the sleeve material slapping the arm, much like the slap of a wet towel. The problem was found to be somewhat unique to the cloth in the army fatigue uniform. It also is most likely to occur when the fatigues are wet (either from rain or sweat). Later groups were warned about this problem and allowed to go bare armed by rolling up their sleeves, wearing only a T-shirt, or wearing a field jacket. All these approaches worked and this phenomenon was not a problem for later groups.

b. Acceptability Charts/Elective Failures

For this study distance, the subjects were not asked to fill out a questionnaire on acceptability. Some of their opinions can be derived from the number of elective failures as shown below:

Table III-19

Elective Failures
5-m Distance, Modified Muff

Subject	Elected Not To Go To Level 7	Condition Elected Not To Go To	Election Stopped Further Exposure
BBB1	NA	5/6	No
BCC2		6/50	Yes
BCC3		6/100	Yes
BCC4		6/100	Yes
BCC5		6/100	Yes
BDE4		6/12	No
BDE3		6/100	Yes
BEF3		6/12	Yes
BEG5	Yes	6/50	Yes
BFH2	Yes	6/50	Yes
BFH3	Yes	6/50	Yes
BFH5	Yes	6/50	Yes

BFH6	Yes	6/25	Yes
BFI3	Yes	6/50	Yes
BFI2		6/50	Yes
BFI4		6/50	Yes
BFI5		6/50	Yes
BHM3		6/25	Yes

In summary, there were 18 elective failures, 17 of which resulted in the stopping of further exposure. There were also 6 subjects of 56 eligible who elected not to go to Level 7. (Note: A decision not to go to Level 7 never resulted in the stoppage of the exposure of a subject. The subject was always eligible to go to condition 6/12.) Of the 17 subjects who elected to stop after reaching Level 6, the average number of shots that was refused was 54, implying condition 6/50 was found unacceptable by more than 20% of the subjects.

c. Exit Questionnaires

There are several questions on the exit questionnaire that can provide some insight as to the subjects' opinion of the exposures (Table III-20).

TABLE III-20

VOLUNTEER EXIT QUESTIONNAIRE SUMMARY

Question	Group	Response			
		Excellent	Good	Fair	Poor
Please rate the following aspects of your participation in the study check: EXCELLENT.....if you think it could not be better GOOD.....if you think there is some room for improvement FAIR.....if you think there is alot of room for improvement POOR.....if you think it is very unsatisfactory					
1. Information you received before you agreed to participate in this study?	P	6	1		
	C	24	22	4	
	D	32	21	3	
	M	22	17	11	7
	B	26	21	2	

2. How easy was it to get questions answered that you might have had about being part of the study?	P	7			
	C	34	14	2	
	D	35	17	3	1
	M	31	23	3	
	B	35	14		
3. Accuracy of information provided when you were recruited concerning medical tests you would be subject to?	P	7			
	C	24	18	3	
	D	32	22	1	1
	M	35	16	6	
	B	29	18	2	
4. Accuracy of information provided when you were recruited regarding the effects on you of actual blasts?	P	6	1		
	C	26	18	4	
	D	24	25	4	
	M	27	25	5	
	B	25	22	2	

Please read the following information and state whether you agree or disagree with the statement.....

Question	Group	Strongly Agree	Agree	Disagree	Strongly Disagree
1. All of my questions were answered before I agreed to come to Albuquerque and be a part of this study?	P	3	4		
	C	20	27	3	
	D	22	26	6	
	M	16	30	10	1
	B	14	32	3	
2. I felt pressured into agreeing to participate in this study.	P			4	2
	C			15	35
	D	1	1	13	38
	M		1	11	45
	B		2	8	39
3. The laryngoscopic exams were uncomfortable and I would have preferred they had not been done.	P	1	4	1	1
	C	8	18	15	9
	D	17	15	20	2
	M	8	20	28	1
	B	4	20	18	7
4. The actual blas[illegible] [illegible]ere more intense than I expec[illegible]	P		3	2	2
	C	6	22	17	5
	D	2	27	20	3
	M	7	23	22	5
	B	1	22	19	7

5. The physical discomfort I felt from the blasts was worse than I anticipated.	P			5	2
	C	3	16	25	6
	D	1	10	36	6
	M		9	34	8
	B	3	7	26	13
6. I was mentally bothered by the blasts.	P			4	3
	C		6	20	23
	D		5	22	28
	M		2	20	34
	B		4	13	32
7. Medical personnel always told me what to expect during examinations.	P	2	5		
	C	26	23	1	
	D	18	33	2	2
	M	24	30	2	1
	B	22	23	3	1
8. I need more break time between medical exams and tests.	P			4	3
	C	2	7	31	9
	D		6	35	15
	M		4	42	10
	B	1	4	30	14
9. My mental attitude was improved by participating in this study.	P	1	6		
	C	7	2	9	
	D	8	35	9	
	M	4	28	18	3
	B	6	23	19	1
10. The medical personnel had time to do a good job.	P	1	6		
	C	15	34	1	
	D	18	36	2	
	M	18	37	2	
	B	15	34		
11. I felt the military staff involved in the study were concerned about me personally.	P	3	4		
	C	26	19	3	
	D	26	25	3	
	M	33	20	4	
	B	36	21	2	
12. My sleep pattern was disturbed during my participation in this study.	P		1	3	3
	C	4	2	34	10
	D	2	4	31	19
	M	1	9	35	12
	B	1	4	35	29
13. I'm glad I agreed to participate in this study.	P	3	3	1	
	C	32	18		
	D	34	19		
	M	43	12		1
	B	31	1	1	

14. I think my being a part of this study will benefit military personnel.	P	3	4		
	C	21	29		
	D	33	19	1	
	M	29	25	1	
	B	20	26	2	
15. I would recommend to others that they agree to be a participant in this study.	P	3	4		
	C	27	22	1	
	D	26	25	2	
	M	26	29	1	
	B	24	20	3	1
16. The medical personnel treated me with care and concern.	P	3	4		
	C	23	27		
	D	29	25		
	M	25	31		
	B	27	31	1	
17. Being a part of this study will benefit me later in life.	P	2	5		
	C	11	25	9	
	D	15	25	9	1
	M	9	32	15	
	B	7	29	8	3

d. Rank Order Charts

Not done for this study distance. See next study distance "M."

e. Medical Data

The medical data were analyzed in several ways. First, a complete listing of all the symptoms and complaints and physical measurements had been provided to the medical staff at Walter Reed. Their review has not resulted in any significant findings. Second, the incidents listed in this report are perhaps the best measure of non-auditory considerations. Finally, Table III-21 and III-22 perhaps provide a good indicator of any general medical problems that might have been related to an increasing exposure energy. In Table III-22, the number of incidents with respect to the nose (such as a runny or stuffy nose from a cold) and the mouth and throat (such as a sore throat) are listed for each energy level. By energy level it is meant, in this case, energy level 1 corresponds to the exposure condition of six shots at Level 1. Likewise, energy level 7 corresponds to Level 7 at 6 shots, Level 6 at 12 shots, Level 5 at 25 shots, Level 4 at 50 shots, or Level 3 at 100 shots. Similarly, energy level 10 corresponds to Level 6 at 100 shots.

The nose and mouth were separated because of the greater number of entries (Figure III-22) for these questions. Figure III-23 shows the percentage of time that the problems were reported out of the total number of possible responses.

TABLE III-21

Number of Positive Responses to Daily Medical Questionnaire with Respect to Questions on Nose, and Questions on Mouth/Throat

DISTANCE B

ENERGY LEVEL	NOSE # TRUE	MOUTH #TRUE	TOTAL RESPONSES
1	9	10	62
2	8	8	62
3	8	6	57
4	8	10	66
5	4	8	63
6	8	5	62
7	8	7	116
8	0	1	57
9	1	1	44
10	2	2	44

DISTANCE C

ENERGY LEVEL	NOSE # TRUE	MOUTH #TRUE	TOTAL RESPONSES
1	3	9	88
2	1	3	88
3	0	7	85
4	0	5	86
5	1	5	79
6	2	5	80
7	2	9	124
8	2	5	64
9	1	3	64
10	0	5	34

DISTANCE D

ENERGY LEVEL	NOSE # TRUE	MOUTH #TRUE	TOTAL RESPONSES
1	3	7	66
2	1	4	68
3	3	12	67
4	1	9	66
5	1	6	70
6	2	3	70
7	2	9	131
8	0	4	71
9	5	4	68
10	1	2	28

DISTANCE M

ENERGY LEVEL	NOSE # TRUE	MOUTH #TRUE	TOTAL RESPONSES
1	3	8	59
2	5	13	59
3	4	9	59
4	6	8	58
5	3	6	60
6	6	10	65
7	3	8	114
8	2	4	56
9	4	8	57
10	3	6	55

DISTANCE P

ENERGY LEVEL	NOSE # TRUE	MOUTH #TRUE	TOTAL RESPONSES
1	0	1	20
2	0	1	21
3	0	1	24
4	0	1	26
5	0	2	35
6	1	1	21
7	2	2	26
8	0	0	7
9	0	0	3
10	0	0	1

TABLE III-22

Summation of TRUE Values for Medical Data

GROUP DATA

ENERGY LEVEL	B # TRUE	B TOTAL	C # TRUE	C TOTAL	D # TRUE	D TOTAL	M # TRUE	M TOTAL	P # TRUE	P TOTAL
1	3	64	2	88	6	66	1	59	3	20
2	0	60	3	87	4	68	2	59	2	21
3	2	62	1	85	1	67	4	59	1	24
4	5	66	0	86	5	66	1	58	0	26
5	5	65	2	88	4	69	4	60	1	35
6	3	63	2	80	2	70	3	64	2	19
7	7	113	6	202	1	126	1	113	1	28
8	1	57	3	65	4	71	4	58	0	7
9	0	44	1	64	4	68	3	57	0	3
10	0	44	0	33	6	28	1	55	0	1

Note: The values are for Eyes, Sinuses, Ears, Chest, Heart, and Abdomen.

In Table III-22, the remaining possible responses are summed and reported for each study condition or the energy levels from 1 to 10. Most of these entries either came from the daily medical questionnaire given the subjects or from the daily physical examination. An example of this questionnaire is given in Appendix A. Figure III-24 summarizes the percentage of time vs. energy level subjects reported some medical problem other than nose or throat.

2. 5-m Distance, Modified Muff

a. Non-Auditory Injury

There was only one case of non-auditory injury. During the out-processing physical, subject MFJ5 did show definite petechiae that the examining doctor believed to be most likely blast related. This examination came approximately 48 hr after the last blast exposure. This was the first detection of petechiae since the first group in October 1989 and the first subject to show detectable petechiae during the exit physical. The only difference with this subject was that he did so after 500 pushups between Shots 1 and 90 on the 100-shot day. However, at least three other subjects have accomplished this feat without any noticeable effect. Note: Strenuous activity such as pushups has not been encouraged nor forbidden except it is forbidden within 12 minutes of the first post-exposure audiogram.

b. Acceptability Charts/Elective Failures

(1). Questionnaire 1. Starting with the November 1990 group of subjects, the subjects who finished the matrix were asked to provide an opinion as to the "acceptability to train" as they would individually define such a term. For the conditions which they were not exposed, they were allowed to extrapolate. For instance, almost all of the subjects were exposed to both 6 shots at Level 5 and 100 shots at Level 6. From these exposures, the subjects projected their thoughts about 100 shots at Level 5. Figure III-25 is a summary of the results.

There are a couple of interesting observations that can be made. The first one is that none of the subjects found the 6/6 exposure unacceptable while 16 subjects thought the step up to 7/6 unacceptable. Obviously, there was a very sharp break perceived by some of the subjects between Levels 6 and 7. The second observation is the importance of the number of shots. While condition 6/6 was considered acceptable by all, condition 6/50, which was about eight times more shots, was unacceptable to over 40% of the subjects. Clearly, when shooting 1 shot per minute, the number of shots is an important parameter in terms of acceptability. The PI suspects that increasing the number of shots per minute, so less time would be spent on the test pad, would have made the 50- and 100-shot days somewhat more acceptable.

(2) Questionnaire 2. After the subjects were given the first questionnaire, a second questionnaire was given to the subjects. This questionnaire provides a finer breakout. The questions and the results of these questions are summarized in Figure III-26. There were only 46 responses instead of 47 because one sheet was either lost or never filled in.

The results to these questions basically follow the results of only using acceptable/nonacceptable.

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

In order 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 (see Figure III-27). Information as to what was meant by acceptablity was not provided. In fact, the subjects were told that acceptability was up to them to define individually. The subjects were told that in Sample 1 the person thought that there was little difference between Levels 1, 2, and 3 and a large difference between Levels 6 and 7. Sample 2 depicted a person that thought the steps between each level were the same.

Sample 3 demonstrated a person who thought there was little difference between Levels 6 and 7 but a substantial difference between Levels 1 and 2.

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

Sixty-three subjects participated in the questionnaire since its inception in August 1990. The mean scores were as follows:

Table III-23
Summary Acceptability Questionnaire

Level	Average Score
1	1.0
2	1.8
3	4.7
4	8.9
5	14.7
6	22.6
7	31.0*

* Levels 1 and 7 were fixed for each subject as 1 and 31, respectively.

Besides looking to average scores, it is informative to look at the change between levels in which the subject indicated the largest step size. Figure III-28 shows such an example.

Figure III-29 shows the percent of the subjects that gave the change between one level and the next level six or more units.

The general trend is for the step size to increase with level. However,the subjects ranked the step from Level 5 to Level 6 (Step 5-6) almost as great as the step from Level 6 to Level 7 (Step 6-7). Both Figures III-28 and III-29 show the lack of difference between Steps 5-6 and 6-7. The step from Level 5 to Level 6 certainly catches the attention of the subjects. In the principal investigator's own experience, the chest wall movement is the dominating feeling at Level 6. Perhaps this effect leads to a clear break between Levels 5 and 6. However, it is interesting to note that 25% of the subjects selected lower steps at the greatest. We expect that the transition between almost an auditory sensation at the low levels to a non-auditory sensation at high levels may account for this.

The main purpose of this questionnaire was to see if a well-defined subjective exposure limit would become obvious. Analyzing these results by themselves such as a limit is not indicated. While the principal investigator believes that designing weapons to Level 7 would be a mistake from user acceptance, well motivated soldiers could clearly use weapons that produced exposures such as Level 7.

The summary of elective failures follows:

Table III-24

Summary of Elective Failures

Subject	Level 7 Elective Failure	Condition to Which Elected Not to Go	Election Stopped Further Exposure
MBC3	Yes		No
MFJ1	Yes		No
MFK6		4/6	Yes

In summary, there was only one elective failure that stopped the subject's exposure. Only two of the 55 subjects eligible elected not to go to Level 7.

c. Exit Questionnaire

The results of the exit questionnaire is shown in Table III-20.

d. Medical Data

The results are reported in the previous distance and are summarized in Tables III-21 and III-22.

3. 1-m Distance, Modified Muff

a. Non-Auditory Injury

There were three non-auditory failures after condition 6/100. Subject DAB1 was positive with respect to petechiae. Recovery was complete over a weekend. During condition 6/50, shot 14 loosened an impacted wisdom tooth of subject DBC6. After Shot 17, he came off the pad. The medical monitor dropped him from

further exposure. Subject DBD6 had a hematoma on his right tympanic membrane from exposure to 6/12 on 12 October. While subject recovered by 16 October, the medical monitor elected to drop subject from further exposure. It should be noted that exposure of two other subjects was stopped because of touch football injuries. Subject DBD1 was diagnosed as having a rib fracture and his exposures were stopped after 6/25. Likewise, Subject DBC3 elected to stop because of a sore rib cage.

b. Acceptability/Elective Failure.

The acceptability of the mortar distance "D" is shown by Figure III-31. The subjects were not exposed to all conditions, of course, but they were asked to provide their best judgement as to the acceptability of the conditions they did not receive. The results show clearly that condition 6/100 is the least acceptable. Conditions 6/25, 5/50, and 5/100 are the next least acceptable. It is interesting to note that there is a distinct break between the above six conditions and the rest of the conditions of the matrix. The subjects were comfortable with the conditions at Level 4 and below. Note also, as with the 5-m distance, the dramatic difference between conditions 7/6 and 6/6. Perhaps exposure to large number impulses at Level 6 provided adaptation so a few shots at Level 6 did not seem so bad.

Figure III-32 illustrates the data from asking the subjects simply if the condition is acceptable or not. The results seem comparable to the more detailed questionnaire except that the 4/100 condition shows less acceptability.

The summary of elective failures follows:

Table III-25

Summary of Elective Failures

Subject	Level 7 Elective Failure	Condition Elected Not to Go To	Election Stopped Exposure
DAA5*	Yes*	6/100*	Yes*
DBC3		6/12	Yes**
DCF5		4/100	Yes*
DCF5*		6/100*	Yes
DDH4		6/100	Yes
DEI1		6/50	Yes
DEJ4		2/6	Yes

DEJ5		3/50	Yes
DFK6		5/100	No
DFL6		3/6	Yes
DFL4		6/50	Yes
DFL3		6/50	Yes

* Second-level hearing protection.
** Stopped only first-level exposures.

Of the 65 subjects who started the study, there were 10 elective failures with first-level protection and two elective failures with second-level protection. Six of the failures were against either condition 6/50 or 6/100.

c. Exit Questionnaires

The results of the exit questionnaire are shown in Table III-20.

d. Rank Order Charts

After a subject has been exposed to Level 7, he is asked to compare the levels by placing the Levels 2-6 between Levels 1 and 7 as shown in Figure III-33. The results of the 55 subjects exposed up to Level 7 while wearing first-level hearing protection is shown. It should be noted that, on the average, there is more of a gap between Level 5 and Level 6 than between Levels 6 and 7. In fact, more subjects (20) listed the jump from Level 5 to 6 as the greatest than the jump from Level 6 to 7 (10 subjects). For this questionnaire, a distinct break in subject attitude occurs past Level 5. However, when this questionnaire was given, the subjects were not exposed to more than six shots at a time.

e. Medical Data

The medical data are summarized in Tables III-21 and III-22.

4. 3-m Distance, Modified Muff

a. Non-Auditory and Other

There were no non-auditory failures. There was one elective failure that can be traced to non-auditory discomfort. This was subject CFJ4.

After condition 6/25, this subject complained of a sore throat. He stated that each blast further bothered his throat.

He was sent to Lovelace Medical Center for a laryngoscopic exam. This exam was negative but the physician did recommend that he not be exposed while he had a sore throat. The subject was willing to continue exposures at Level 5 if he could be assured that his throat would not be affected again. The principal investigator was unwilling to guarantee this, so the subject was not exposed further. The scoring of this subject is uncertain as it could be considered either a non-auditory failure or an elective failure. However, the principal investigator scored it as an elective failure because the subject was unwilling even to try a few shots.

All stool guaiacs and laryngoscopic examinations were negative.

b. Acceptability/Elective Failures

The overall acceptability of training at the various exposure conditions was requested of the subjects after they had completed their last exposure of the regular study (prior to the no-countdown study where applicable). The results are shown in Figure III-34 show that condition 6/100 is the least acceptable. As with the mortar distance, conditions 7/6, 6/50, and 5/100 are the next least acceptable. Similar to the mortar, there is a considerable difference between conditions 6/6 and 7/6. Figure III-35 is the data from asking the subjects simply if the condition was acceptable or not. These data appear to be comparable to the more detailed questionnaire except condition 4/100 showed less acceptability and condition 5/50 showed more.

The summary of the elective failures is as follows:

Table III-26

Summary of Elective Failures
3-m Distance, Modified Muff

Subject	Level 7 Elective Failures	Condition Elected Not To Go To	Election Stopped Further Exposure
CAA3	Yes (1 shot)		No
CAB3	Yes (2 Shots)		No
CAB6	Yes (2 shots)		No
CBC1		6/25	Yes

CBC6			No
CCD1	Yes	6/50	Yes
CCD5		6/50	Yes
CCE1		4/50	Yes
CCE2		6/100	Yes
CCE4	Yes	6/100	Yes
CCE5		6/100	Yes
CDF2	Yes		No
CDF3	Yes	6/100	Yes
CDF5	Yes	6/100	No
CDG2	Yes (1 shot)	6/100 (59 shots)	Yes
CDG3	Yes		
CEH2		6/25 (9 shots)	Yes
CFJ6		6/50	No
CFJ4		6/50	Yes
CFK2		5/100	Yes
CGL4	Yes		
CGM1	Yes		
CGM2	Yes		
CGM5	Yes		

In summary, there were 24 elective failures for the 68 subjects who started. However, 11 of these were only against condition 7/6 and did not affect the subjects finishing the study.

c. Rank Order Charts

After a subject had been exposed to Level 7, he was asked to compare the levels by placing the Levels 2 to 6 between Levels 1 and 7 as shown in Figure III-36. The results of the 46 subjects exposed up to Level 7 while wearing first-level hearing protection are shown. It should be noted that, on the average, there is a slightly greater gap between Levels 5 and 6 than between Levels 6 and 7. In addition, as many subjects (15) listed the jump from Level 5 to 6 as great as the jump from Level 6 to 7. As with the previous distances, there seems to be a distinct break in subject attitude that occurs past Level 5. As before, when this questionnaire was given, the subjects had not been exposed to more than six shots at a time.

d. Medical Data

See Tables III-21 and III-22.

5. 3-m Distance, Modified Muff, No-Countdown

a. Non-Auditory Injury

There were no non-auditory failures.

b. Acceptability/Elective Failures

Twenty subjects started and only four completed all six shots at Level 7. Fifteen of the 17 subjects that were stopped were elective failures. In summary, 20 passed Level 1, 18 passed Level 2, 13 passed Level 3 (1 conditional failure did not pass), 13 passed Level 4, 8 passed Level 5, 8 passed Level 6, and 4 passed Level 6.

There were some steps in which more subjects left than others. For instance, five subjects quit after Level 2, five subjects quit after Level 4, and four subjects quit after Level 6. No subjects quit after Level 3 or 5.

Clearly, most subjects did not like the surprise of a no-countdown exposure. Weapon designers might well be somewhat cautious of designing weapons in which the time of firing is not predictable. On a positive note, the four subjects that passed Level 7 had no qualms about the no-countdown exposures.

6. 3-m Distance, Perforated Muff

a. Non-Auditory Failures

For the 19 subjects starting the study, there was one non-auditory failure that occurred. Subject PAB5 had on hematoma on his right tympanic membrane after condition 4/6. Recovery was complete in 10 days. Subsequently, he was exposed to one shot at Level 4 without any evidence of reoccurrence of the hematoma. However, the PI was unwilling to expose these subjects to multiple shots at Level 4 without observing the tympanic membrane after each shot. Therefore, further exposures were restricted to Level 3 or below.

There was also a non-auditory incident in that subject PAA6 had a hematoma on his left ear canal following condition 4/6. This was believed to be due to movement of the E.A.R.® plug. Recovery was within a day and the subject continued without incident. However, because he was an audiometric failure in his right ear, he was never again exposed to Level 4.

b. Acceptability/Elective Failures

A formal questionnaire was never given to the subjects for several reasons. First, the subjects made it very clear that they disliked the perforated plug for any exposure condition. Second, because of the rapidity of which the matrix cells were closed out, none of the subjects ever had a chance to experience the more energetic matrix conditions. Finally, there were too few subjects in any case. The subjects were asked why they had such a strong dislike of the perforated plug. They complained about the lack of comfort. They also thought it was illogical to have a hole in the plug, but they especially complained of the difficulty to hear the countdown when the wind exceeded approximately 10 mph. The wind caused a whistling sound across the opening when the orientation was right. This whistling sound interferes with speech reception. With the foam plugs they did not have as much trouble hearing the countdown although the attenuation is greater. Thus, the only reason for using the perforated plugs, i.e., better speech reception, is not valid under windy conditions.

Because of the subjects lack of confidence in the plug and because of the large number of audiometric failures, a greater number than previous elective failures occurred. These were:

Table III-27

Acceptability/Elective Failures

Subject	Level 7 Elective Failure	Condition Subject Elected Not to Go	Election Stopped Further Exposure
PAA4	Yes		
PAA5	Yes		
PAA6	N/A	3/100	Yes
PAA7	N/A	3/25	Yes
PAB1	Yes		
PAB2	N/A	3/100	Yes
PAB3*	Yes		
PAB4	Yes	2/100	Yes
PAB5	N/A	2/50	Yes
PAB6	Yes		
PBC2*	Yes	6/12	Yes

PBC3	N/A	1/100	Yes**
PBC3*	Yes	6/100	Yes
PBC4		6/50	Yes
PBD1*	Yes	6/25	Yes
PBD2*		6/12	Yes
PDB1	N/A	2/100	Yes**
PDB2	N/A	1/50	Yes**

* Seccnd-level hearing protection
** Level 1 hearing protection only

Of the 19 subjects who started 12 were elective failures. Eight of these elective failures stopped exposures with Level 1 hearing protection only. In addition, cnly one of the six subjects eligible to be exposed to Level 7 accepted. The other five were elective failures for this condition. For the second-level hearing protection, seven subjects started these exposures. Four of the seven opted to skip the Level 7 exposure. In addition, only one of the seven finished the exposure matrix.

c. Rating of Levels

With only one subject reaching Level 7, rating between levels was not reasonable and not done.

d. Exit Questionnaires

The results of the exit questionnaire are shown in Table III-20. For this distance, the first group of 12 subjects were inadvertently not given the questionnaire by the on-site NCO. Thus, the results are for only the last group of 7 subjects.

e. Medical Data

See Tables III-21 and III-22. For this group, the more energetic levels were from subjects with second-level hearing protection.

E. OTHER FINDINGS

At various times during the testing, there were several systematic observations made over a period of time. In late 1990, the M17 chemical defense mask was briefly evaluated. For each study distance, movement of the RACAL® muff was observed. Finally, the incidence of reddening of the tympanic membrane was closely observed from December 1991 to August 1993.

1. Chemical Defense Gear

In December 1990, Fort Rucker loaned EG&G an M17 chemical defense suit for evaluation with respect to the blasts characterized by the 5-m distance. The principal investigator wore the suit for one or two exposures at several levels. The levels and the subjective response wearing the suit is as follows:

Table III-28

Subjective Response to Various Levels To Wearing the M17 Chemical Defense Suit

Wearing Outfit	Date	Level	Effect Compared to No Suit
M17	12/17/90	3	Less
M17	12/18/90	5	Less body but more on right side of face.
M17	12/19/90	6	Little more. More body and about the same on face.
M17	12/20/90	7	Little more. Some body and a little more on right side of face.
M17	1/8/91	7	More. Some body and more on right side of face.

The least comfortable exposure was the Level 5 exposure in that the mask impacted the right side of the face high up on the cheek bone. Surprisingly, this did not happen at Level 6 and only lightly at the first exposure to Level 7. The second exposure to Level 7 had more effect, especially to right side of face. A definite reddening occurred to top part of right cheek. High-speed photography was made of this exposure. From these exposures there obviously is some variability from shot-to-shot. On the other hand, there were no dramatic changes in effects that occurred when the M17 ensemble was worn. While four exposures are not sufficient to prove the acceptability and adequacy of the chemical defense gear at high blast levels, major problems with the gear are expected. However the tolerance limit to multiple exposures might be reached sooner. The M43 mask was also worn once at Level 3. No obvious problems occurred.

The only clear problem that was noted is that the M17 mask is not rugged enough to withstand the more energetic matrix conditions. Specifically, the M17 mask was placed on a dummy and exposed to 100 shots at Level 6B. This is equivalent to approxi-

mately 187-188 dB. The mask was thoroughly checked and only one small preexisting tear on the right side was noted. After 25 shots, an additional tear became evident and continued to grow until after shot 75. The tear finished growing. Its final length was about 7 cm. A second tear was first noticed after shot 50. This was toward the top of the mask. Tear No. 3 was noticed after 80 shots. This 1-cm tear was actually T-shaped with a small tear at right angles to the main tear. Tear No. 4 (0.5-cm long) was not noticed until the 100 shots were finished.

The preexisting tear did not increase in length during the 100 exposures.

2. Eardrum Reddening

Eardrum reddening (or injection of the tympanic membrane) was first noticed during the 1-m distance. While some initial concern was expressed by the physician assistant about this phenomenon, it was quickly observed that this occurs often even in normally healthy persons. Nevertheless, a detailed investigation of this phenomenon was undertaken for the 3-m distance.

The total incidence of eardrum reddening for all the subjects of the 3-m distance is shown in Figure III-37. A plot of the injection rating for the right ear is shown in Figure III-38. The injection rating is the sum of the individual rating divided by the number of subjects. Because most of the subjects either are rated by a 0 (no-injection) or a 1 (mild injection), the plot in Figure III-38 is similar to one that would show percent of any injection. Figure III-39 shows such a plot for the right ear. Figure III-40 is a plot for the left ear.

It is interesting to note that there is a distinct growth in the percent of subjects with injection in the right ear once Level 5 is reached. Over 50 percent of the subjects had injection after Level 7. For the multiple shots at Level 6, more than 40 percent of the subjects have injection in the right ear after exposure. For the left ear, protected by both ear plug and an unmodified muff, the percent of injection did show an effect with exposure level. Because of the blast effects on the left ear, we conclude that the effectiveness of the earplug accounts for only some of the difference. This would support the supposition that at least some of the effect is due to the action of the eustachian tube.

The importance of this phenomenon is questionable. Mild injection is certainly not something to be concerned about as it occurs routinely in persons without blast exposure.

3. Earmuff Movement.

When the exposures were first started in September 1989, extreme caution was taken to ensure the RACAL® muff was not moved in order to assure the results of the PEAT were valid. The microphones for the PEAT were even left in place so that the muffs would not be moved. The subjects were told not to touch their muffs. This strong concern first came into question during the exposures of groups BEG and BEF.

During the 80 exposures to Level 6 for Group BEG, it was noted by several subjects that their muffs were slipping downward. The PI requested that the subjects move the muffs upward where they were more comfortable and would not feel like they were falling off. This movement, of course, means that "subject fit" was being used at this point. To better understand what was happening during the exposures of Group BEF, the location of the earmuff was traced in black pen before the first exposure. The earmuff was again traced in blue after 25 exposures, green after 50 exposures, and red after 75 exposures. The tracing after 100 exposures was eliminated because it would have been on top of the red line in all cases. Thus, the muffs settled into a stable position by the 75th shot. This fit will be called a "blast fit" as opposed to an "experimenter fit" or "subject fit." Since no TTS occurred, this blast fit apparently does not cause a problem with respect to the performance of the muff. Likewise, the subject fit by the members of Group BEG did not cause a performance decrement. The amount of movement of the blast fit averaged about 1/4-inch forward and 1/4-inch downward. This same movement was noted for groups BFH and BFI at Levels 6 and 7. Therefore, for groups BGJ and BGK, a concerted effort was made to determine before the level at which movement first occurs and the progression of muff movement with number of shots. Movement was determined by marking around the subject's earcups with black grease pencils prior to the first exposure. Just prior to the last shot, the earcups location were marked with a red grease pencil. Differences in the markings more than 1/8 inch were considered movement. Table III-29 shows the movement from Level 4, 6-shot exposure, to Level 6, 25-shot exposure.

For the 50- and 100-shot exposures, an additional marking was made on or about the 50th shot. For the 50-shot sequence, two earcups did not move, nine earcups stopped moving afer 25 shots, and five earcups kept moving. In addition, two earcups moved so often that marking the earcups just did not make sense. Five earcups (four subjects) became so uncomfortable or so loose that the subjects were given permission to reset the earcup.

For the 100-shot sequence, 14 of 18 muffs were reset. Much of this resetting was due to the fact that the miniature microphones used for the PEAT test start to rub and cause discomfort after 25 shots. Thus, 14 of the 18 microphones were removed and the subject allowed to readjust his own earcup. If he readjusted

it so it was between the black and red lines, then the PI left the muff alone. In one case, the PI had to ask the subject to readjust the earcup so it was in between these lines.

We believe that the warm weather was responsible for more movement of the earcup than had been seen before. Warmer weather causes more sweat and results in an earcup that can move around the face easier.

At any rate, the lack of significant TTS, even though the earcups do not stay in position, is a beneficial result. Properly trained soldiers in the field should obtain adequate protection from these muffs even though the muffs are self-fit.

Movement was observed for the other study distances. For the modified muffs with the 5-m distance, the muffs moved in a similar manner to the muffs with no holes. In general, the muffs moved over 50 percent of the time once Level 6 was reached.

TABLE III-29

Earcup Movement

No. of Shots/Level	Date	Movement	No. of Earcups That Moved
6/4	6 Jul 90	No	22 Earcups 0 Moved
6/5	9 Jul 90	No	18 Earcups 0 Moved
6/6	10 Jul 90	Yes	18 Earcups 4 Rt-Moved 2-Lt-Moved
6/7	11 Jul 90	Yes	18 Earcups 7 Rt-Moved 5 Lt-Moved
12/6	12 Jul 90	Yes	18 Earcups 5 Rt-Moved 3 Lt-Moved
25/6	13 Jul 90	Yes	18 Earcups 8 Rt-Moved 7 Lt-Moved

F. BLAST LEVELS AND WAVEFORMS

For convenience, most of the time this report refers to one of the levels from 1 to 7. These levels do translate to a specific average peak level, A-duration, A-impulse, etc. A summary of these values is given in Tables III-30 through III-32 for the 5-m, 3-m, and 1-m distances. Note that for the 5-m distances, there were two versions of Level 6. For 25 shots and greater, the weight of the C-4 was slightly reduced. The resulting levels were called 6B. For

the 6- and 12-shot sequences, the level was called 6A. This difference was not used for the 1-m and 3-m distances. In all cases, the measurements were made at a distance from the center of burst and at a height above the ground that was the same as the entrance of the ear canal. The measurement gauges, however, were located in between subjects so as not to be influenced by the presence of a subject.

Figures III-41, III-42, and III-43 are typical waveforms of the blasts for the three study distances.

TABLE III-30

Average Peak Pressures and Durations for the Impulses at 5 m from the Source

Intensity Code	Peak, kPa	Peak, dB	A-duration, ms	B-duration, ms	C-duration, ms	D-duration ms
1	10	174	2.3	15.6	1.7	6.0
2	14	177	2.5	17.4	2.0	7.8
3	19	180	2.6	17.2	2.1	7.8
4	26	182	2.9	18.0	2.3	7.6
5	36	185	2.8	18.9	2.6	8.2
6	49	188	2.9	20.0	2.8	9.9
7	69	191	3.0	21.2	2.8	8.3

* Measured at the entrance to the ear without the subjects.

TABLE III-31

Average Peak Pressures and Durations for the Impulses at 3 m from the Source*

Intensity Code	Peak, kPa	Peak, dB	A-duration, ms	B-duration, ms	C-duration, ms	D-duration ms
1	10	174	1.4	30	[illegible]	2.5
2	16	178	1.4	22	1.0	2.2
3	23	181	1.4	22	0.7	1.9
4	33	184	1.4	24	0.6	1.3
5	48	187	1.6	30	0.6	0.8
6	63	190	1.4	34	0.5	0.7
7	90	193	1.4	61	1.0	1.2

* Measured at the entrance to the ear without the subject.

TABLE III-32

Average Peak Pressures and Durations for the Impulses at 1 m from the Source*

Intensity Code	Peak, kPa	Peak, dB	A-duration, ms	B-duration, ms	C-duration, ms	D-duration ms
1	16	178	1.1	10.8	1.2	2.5
2	23	181	1.0	12.1	1.0	2.2
3	34	185	0.9	9.5	0.7	1.9
4	48	188	0.9	10.8	0.6	1.3
5	66	190	0.8	15.4	0.6	0.8
6	94	193	0.8	53.8	0.5	0.7
7	130	196	0.8	65.0	1.0	1.2

* Measured at the entrance to the ear without the subject.

G. RESULTS OF PRE- AND POST-AUDIOGRAMS

Before each subject is trained in taking audiograms with the HP1000 system, an entrance audiogram was taken by the on-site military audiologist. At first, this was accomplished at the Kirtland AFB Hospital. In the middle of the study, a Grason Stadler Model 1716 audiometer was procured and set up on site. A IAC single-walled audio booth in a very quiet area was used.

Likewise, exit audiograms were taken after the subjects last exposure and just before the subjects were sent to their next duty station.

The results of 259 subjects are shown in Table III-32. A comparison of pre- and post-levels is provided in Figures III-44 and III-45. The slight improvement is assumed to be due to the learning effect. The average subject will have taken at least 75 audiograms between his pre- and post-audiogram.

TABLE III-33

Pre-Study and Post-Study Hearing Threshold Levels
259 subjects

PRE-STUDY HEARING THRESHOLD LEVELS								
Right Ear								
	250 Hz	500 Hz	1K	2K	3K	4K	6K	8K
Average	3.8	5.2	3.6	0.8	2.2	2.8	4.2	4.5
Standard Deviation	4.1	4.5	5.9	5.8	6.3	6.3	7.5	7.2
Left Ear								
	250 Hz	500 Hz	1K	2K	3K	4K	6K	8K
Average	4.2	5.9	4.2	1.6	2.9	5.0	6.2	6.2
Standard Deviation	4.7	5.2	5.1	6.3	6.5	7.0	8.2	7.3

POST-STUDY HEARING THRESHOLD LEVELS								
Right Ear								
	250 Hz	500 Hz	1K	2K	3K	4K	6K	8K
Average	1.8	3.4	2.0	0.3	1.0	1.8	3.8	3.6
Standard Deviation	4.4	5.2	5.3	6.2	6.6	6.6	7.2	7.0
Left Ear								
	250 Hz	500 Hz	1K	2K	3K	4K	6K	8K
Average	2.5	4.4	2.7	0.5	1.9	3.7	5.5	4.7
Standard Deviation	4.7	5.6	5.5	6.5	6.6	7.5	8.3	7.8

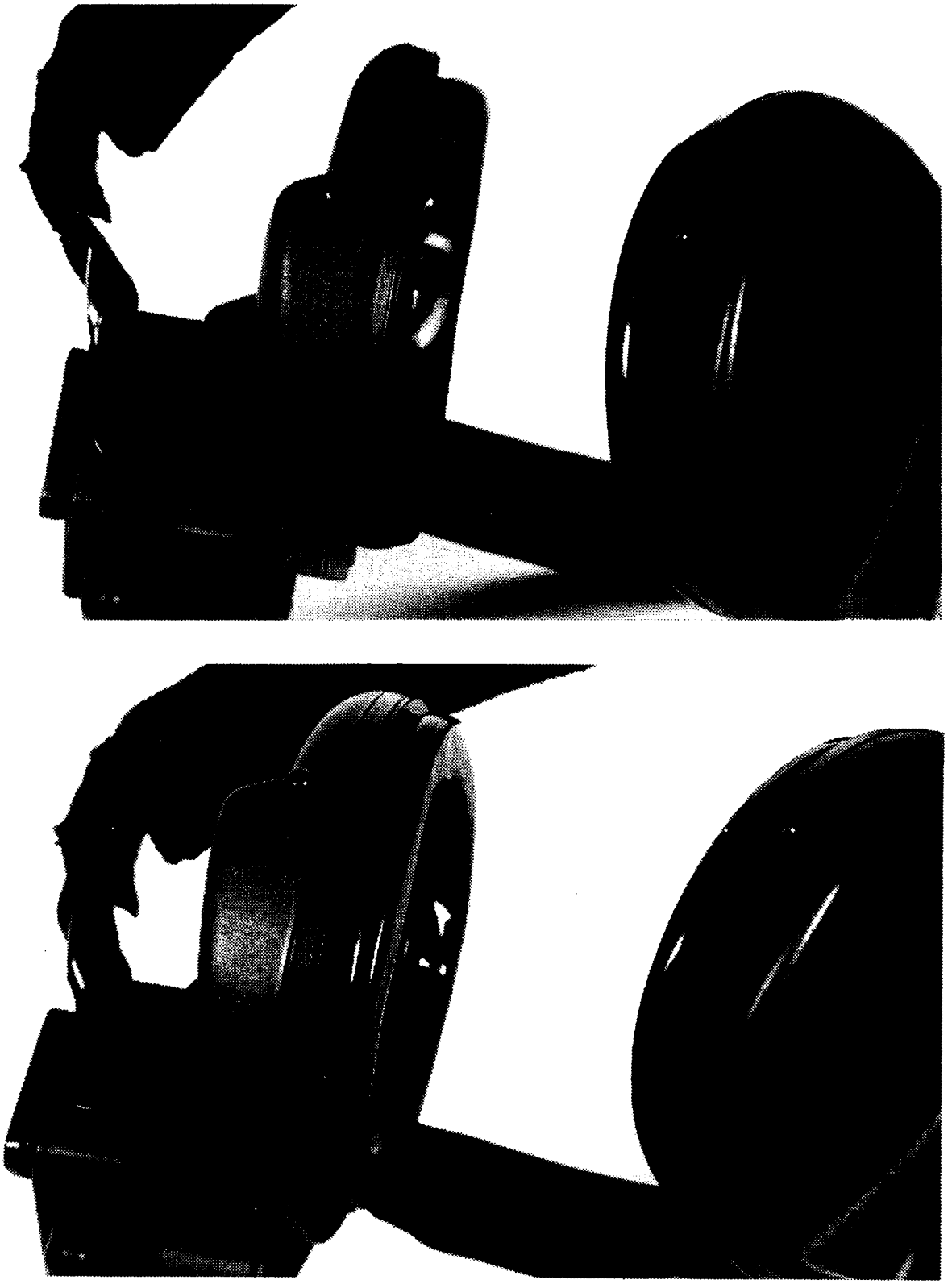


Figure III-1. The RACAL® muff (upper) and the modified RACAL® muff with eight tubes through the right seal (lower).

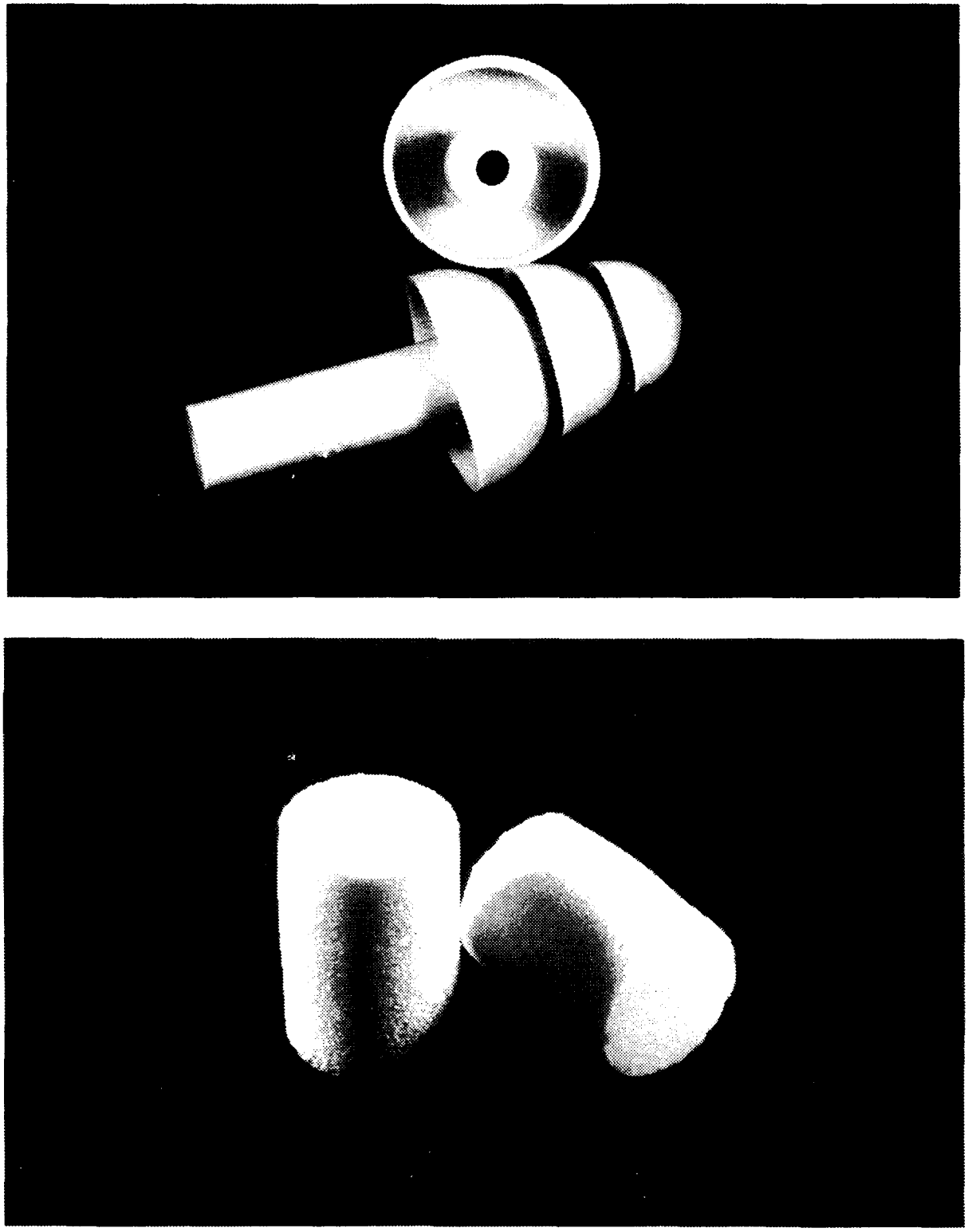


Figure III-2. The perforated plug (upper) and the E.A.R.® foam plug (lower).

Peak pressure in dB SPL	6	12	25	50	100
190	49 0				
188	58 0	56 0	53 0	44 0	39 0
184	59 0	58 0	54 0	45 0	39 0
182	62 0	60 0	56 0	47 0	41 0
179	62 0	60 0	56 0	47 0	41 0
177	62 0	60 0	56 0	47 0	41 0
172	62 0	60 0	56 0	47 0	41 0

Number of impulses

Figure III-3. 5-m distance, unmodified muff. Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for each exposure condition when the standard earmuff was worn.

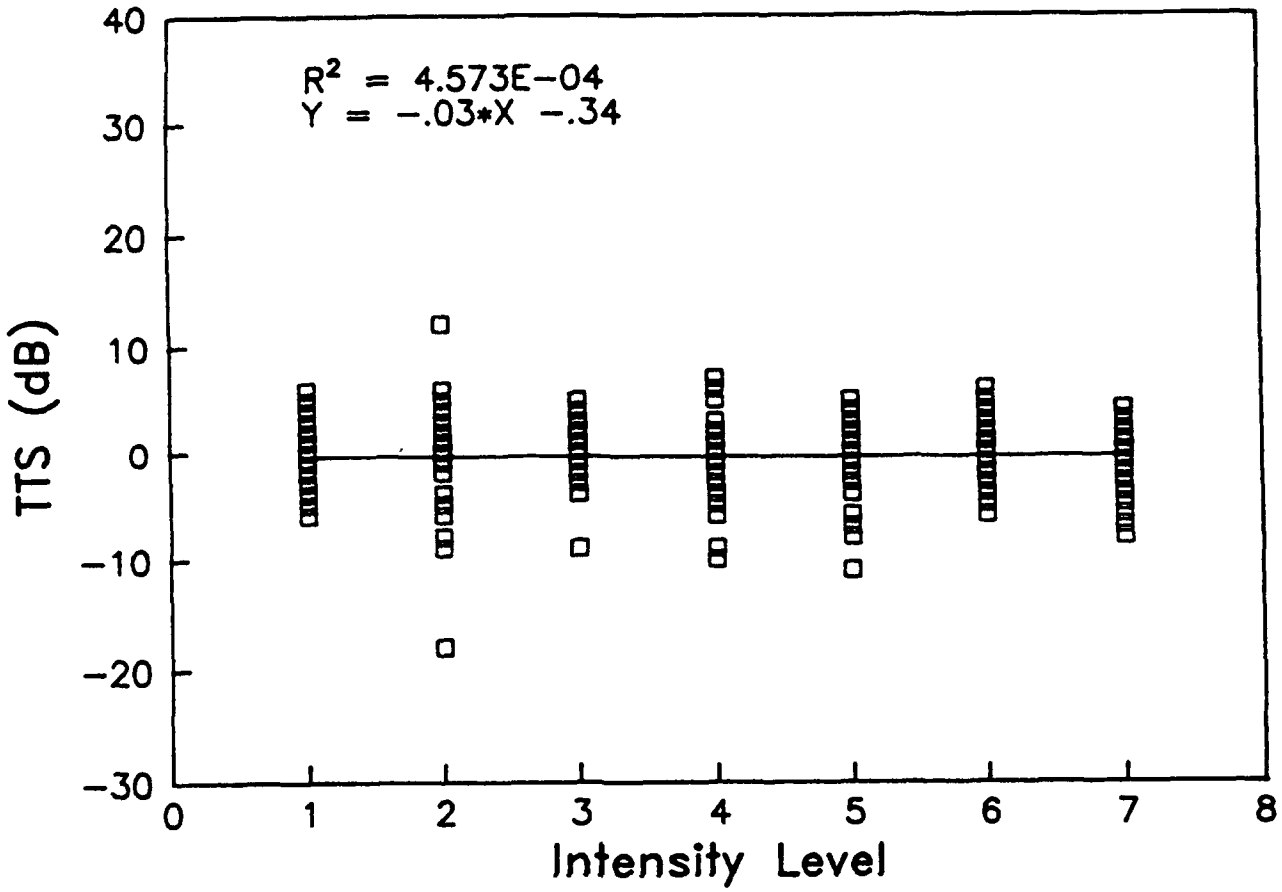


Figure III-4. Regression of TTS vs. intensity level, 5-m distance, unmodified muff, 4000 Hz, right ear.

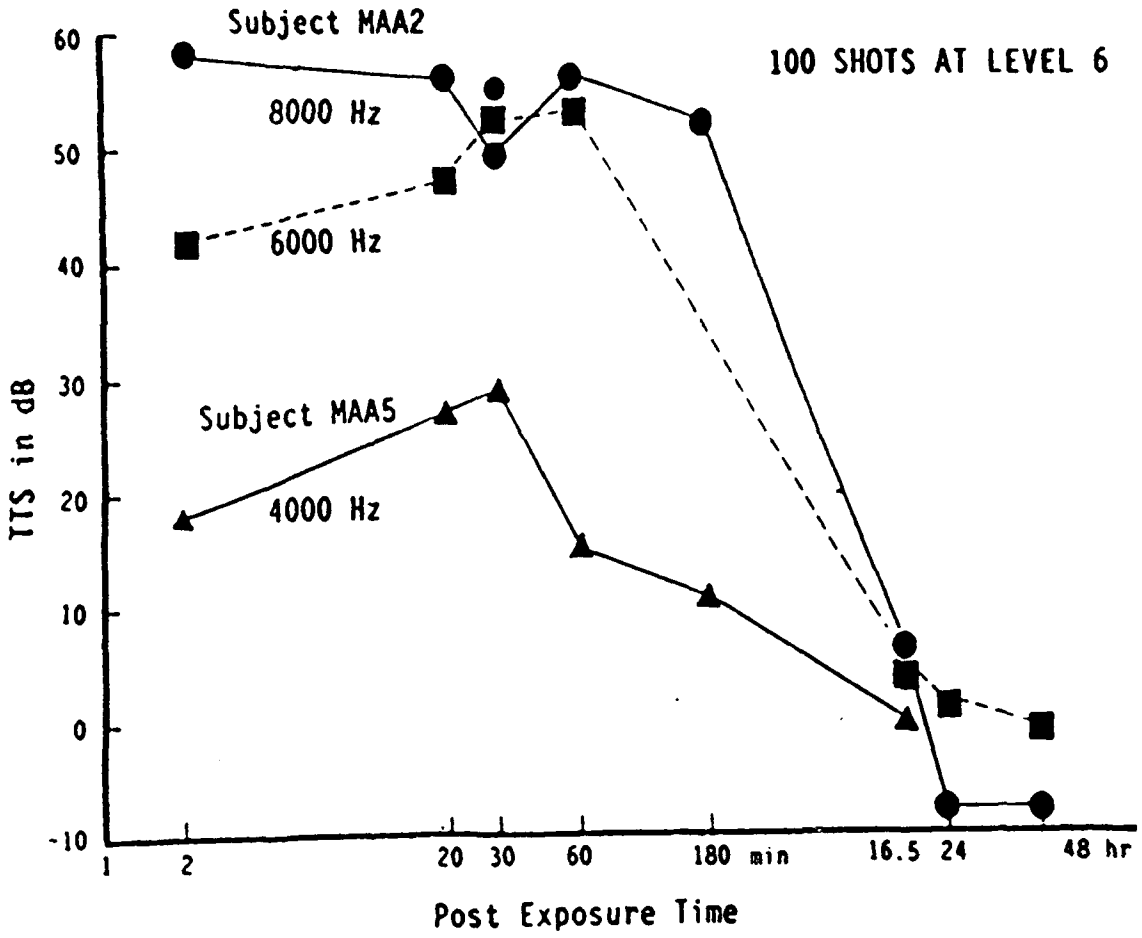


Figure III-5. Summary of TTS and its recovery. Subjects MAA2 and MAA5, 100 shots at level 6.

Level SPL in dB	NUMBER 6	12	25	50	100
7 (190)	54 1				
6 (188)	57 0	56 1	56 1	56 1	53 3
5 (184)	57 0	57 0	56 1	56 1	56 1
4 (182)	58 0	57 0	57 0	56 1	56 1
3 (179)	59 0	57 0	57 0	57 0	56 1
2 (177)	59 0	57 0	57 0	57 0	57 0
1 (172)	59 0	57 0	57 0	57 0	57 0

Figure III-6. 5-Meter Distance - Modified Muff. Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for each exposure condition when modified muff was worn. There was also one non-auditory failure at this condition.

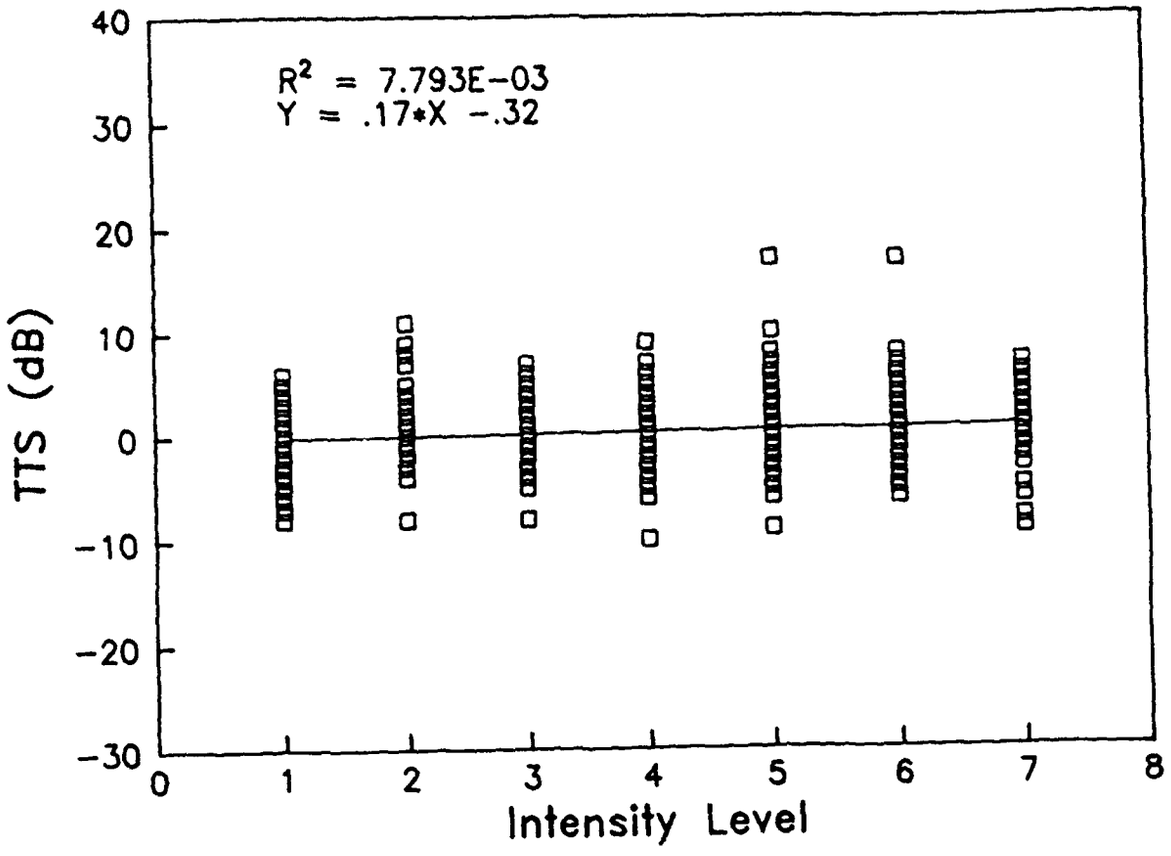


Figure III-7. Regression of TTS vs. intensity level, 5-m distance, modified muff, 6000 Hz, right ear.

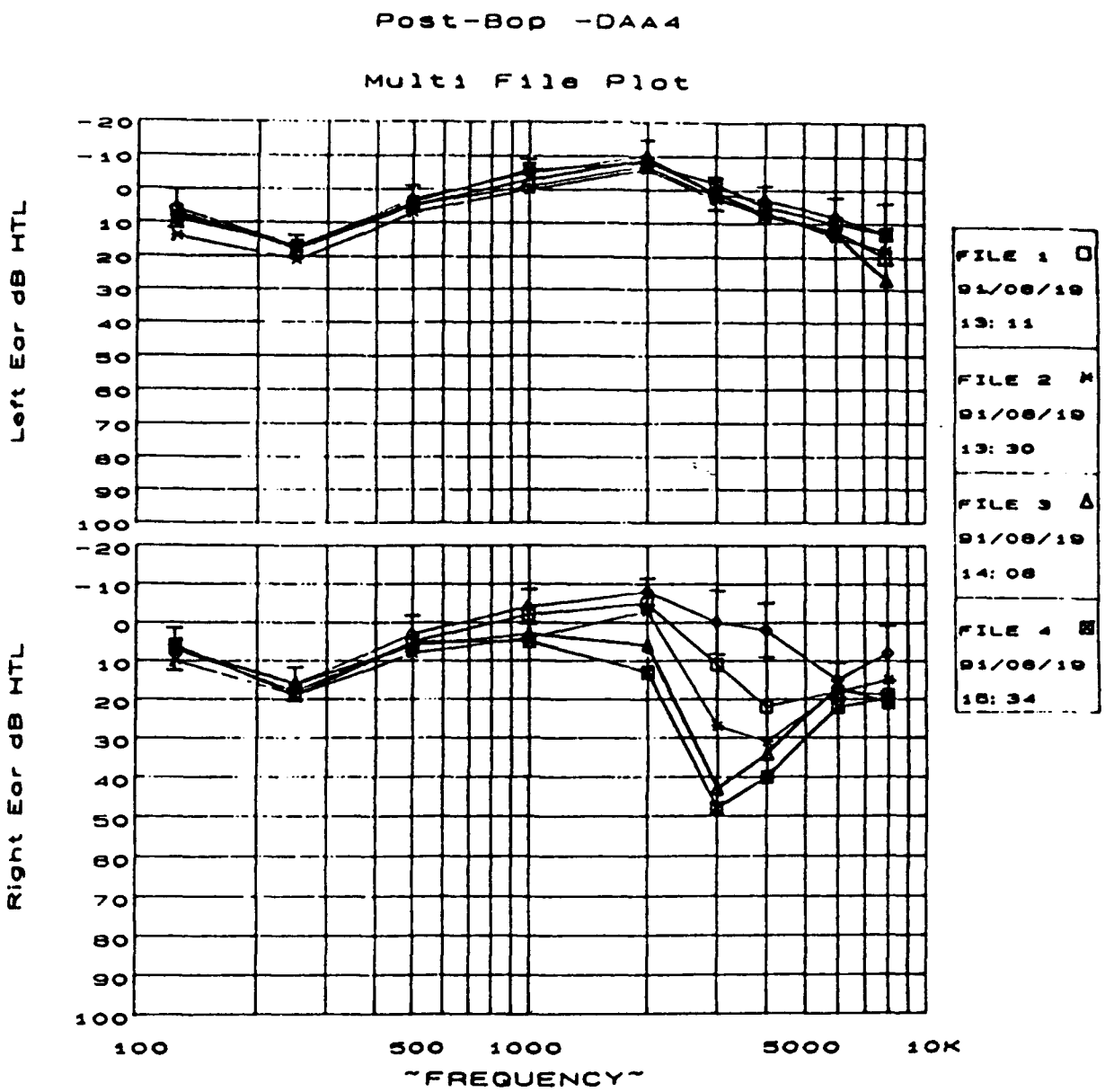


Figure III-8. Growth of TTS for subject DAA4.

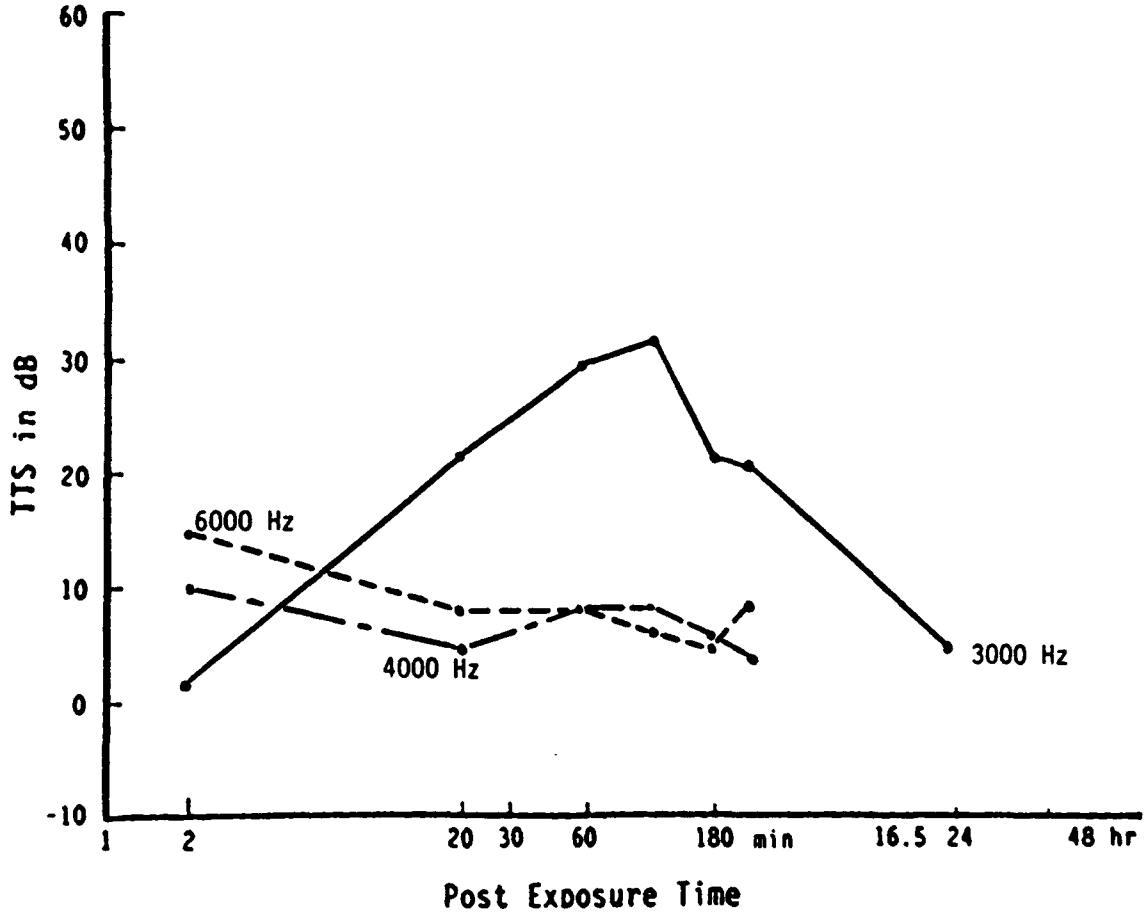


Figure III-9. Summary of TTS growth and its recovery for subject DEJ5. Exposure was six shots at level 7.

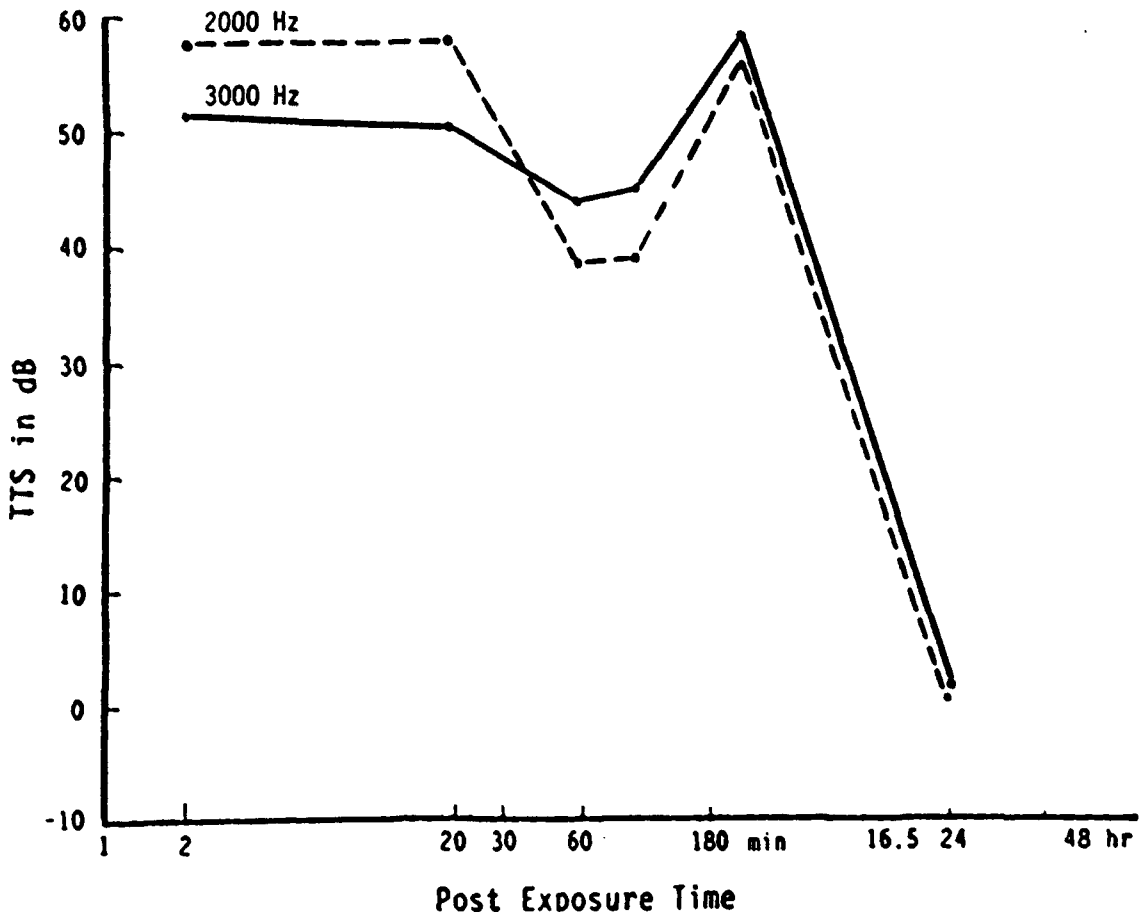
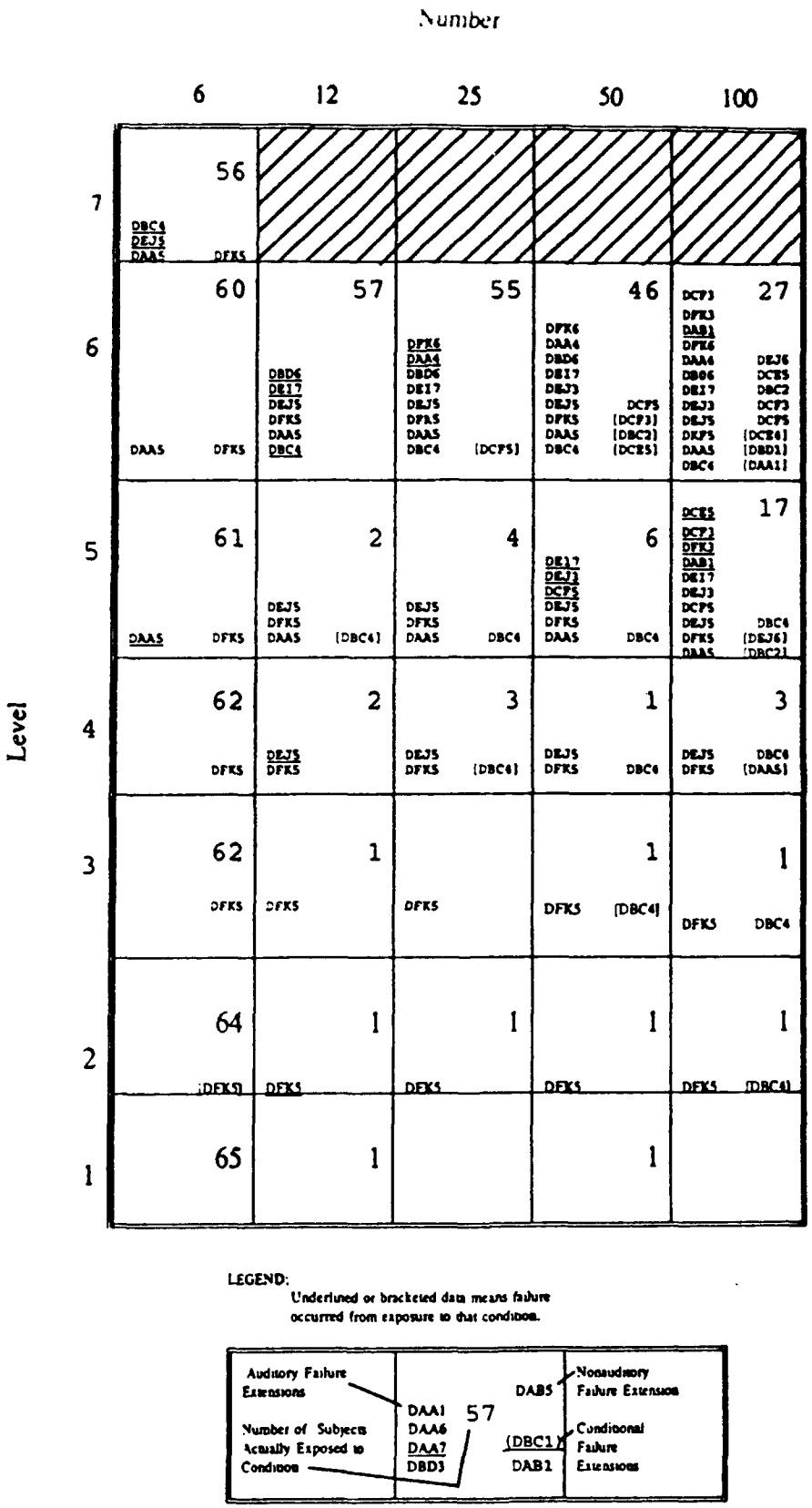


Figure III-10. Summary of TTS and its recovery. Subjects DCF3, 100 shots at level 5.

Level	Number 6	12	25	50	100
7 (196)	55 4				
6 (193)	61 2	55 6	53 8	45 10	26 16
5 (190)	61 2	57 3	55 4	46 7	38 11
4 (187)	62 1	58 2	57 2	47 3	40 3
3 (184)	62 1	58 1	57 1	48 1	41 2
2 (181)	64 0	59 1	58 1	49 1	42 1
1 (178)	65 0	60 0	58 0	49 0	42 0

Figure III-11. Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for each exposure condition when modified muff was worn at 1-m distance.



LEGEND:
Underlined or bracketed data means failure occurred from exposure to that condition.

Figure III-12. Summary of failures for the 1-m distance.

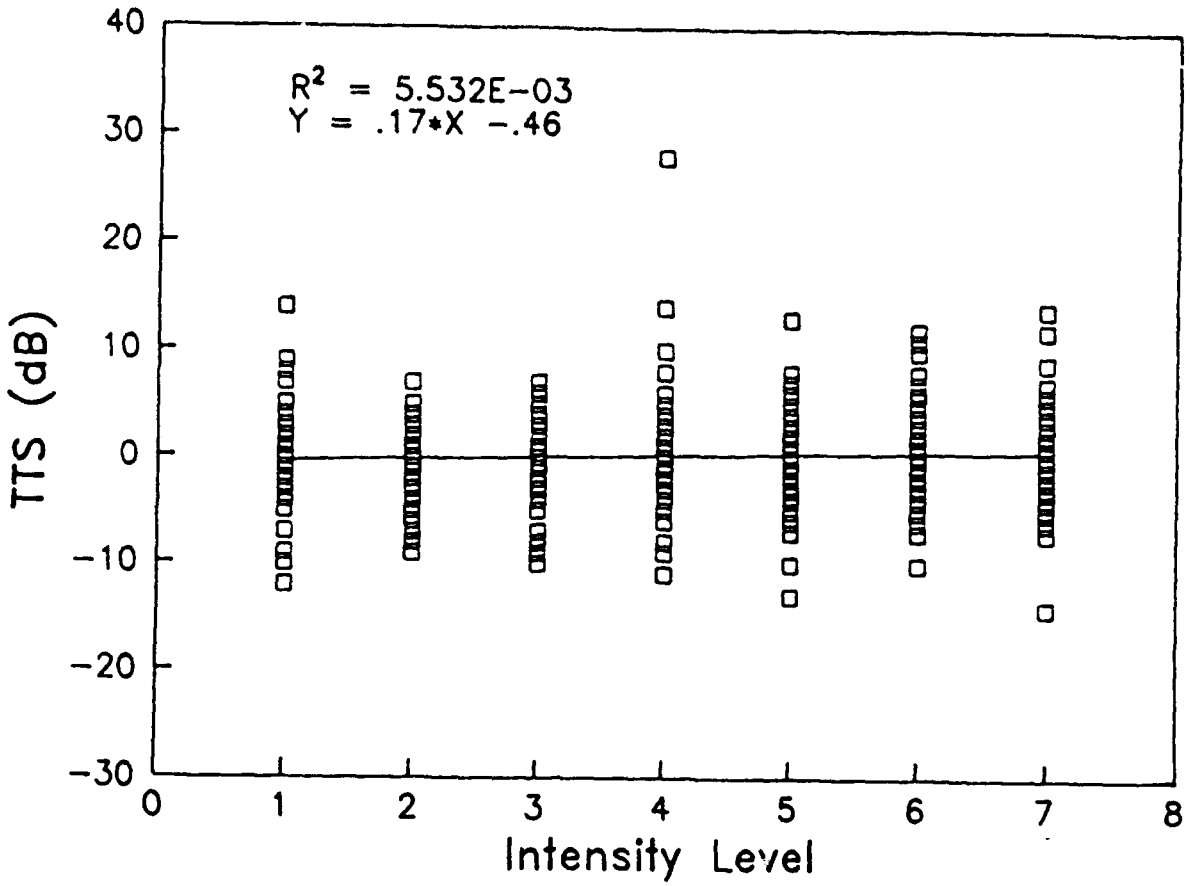


Figure III-13. Regression of TTS vs. intensity level, 1-m distance, 6000 Hz, right ear.

Level	6	12	25	50	100
7	46 pass 5 fail 12 elective 3 admin 1 cond				
6	63 pass. 5 fail	58 pass 6 fail	54 pass 9 fail 1 elective	49 pass 10 fail 4 elective	36 pass 13 fail 4 elective
5	66 pass 2 fail	62 pass 2 fail	61 pass 2 fail	58 pass 3 fail	52 pass 4 fail
4	68 pass	64 pass	62 pass 1 fail	60 pass 1 fail	55 pass 1 fail 1 elective
3	68 pass		63 pass	61 pass	56 pass
2	68 pass				
1	68 pass				

Figure III-14. Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for modified muff at the 3-m distance. (68 subjects started.)

Level \ Number	6	12	25	50	100
7	46 [CGL3] [CFK3] CFJ5 CAA4 CCE1 CCE3 CFK2				
6	61 CFJ5 CCE1 CAA4 CFK2 CCE3	59 CAA6 CFJ5 CCE1 CAA4 CFK2 CCE3	CFJ7 CAB5 CAA6 CFJ5 CCE1 CAA4 CFK2 CCE3 57	CFC4 CAA3 CFJ7 CAB5 CFJ5 CCE1 CAA4 CFK2 CAA6 CCE3 50	CBC3 CBC5 CBC4 CAA3 CFJ7 CAB5 CFJ5 CCE1 CAA4 CFK2 CAA6 CCE3 25
5	67 CFK2 CCE3 [CAA4]	6 CFK2 CCE3 [CAA4]	6 CFK2 CCE3	6 CCE1 CCE3 CFK2 [CAA6]	19 CCE1 CCE3 CFK2 CAA6
4	68 [CCE3]	8 [CCE3]	2 CCE3	1 CCE3	1 CCE3 [CAA6]
3	68	3	1		
2	68	1		1	
1	68				

LEGEND:

Underlined or bracketed [ ] data means failure occurred from exposure to that condition.

Auditory Failure Extensions	CAB5	Nonauditory Failure Extension
Number of Subjects Actually Exposed to Condition	59 CAA1 CAA6 CAA7 CBD3	Conditional Failure Extensions
	CBC1 (CAB1)	

Figure III-15. Summary of failures for the 3-m distance.

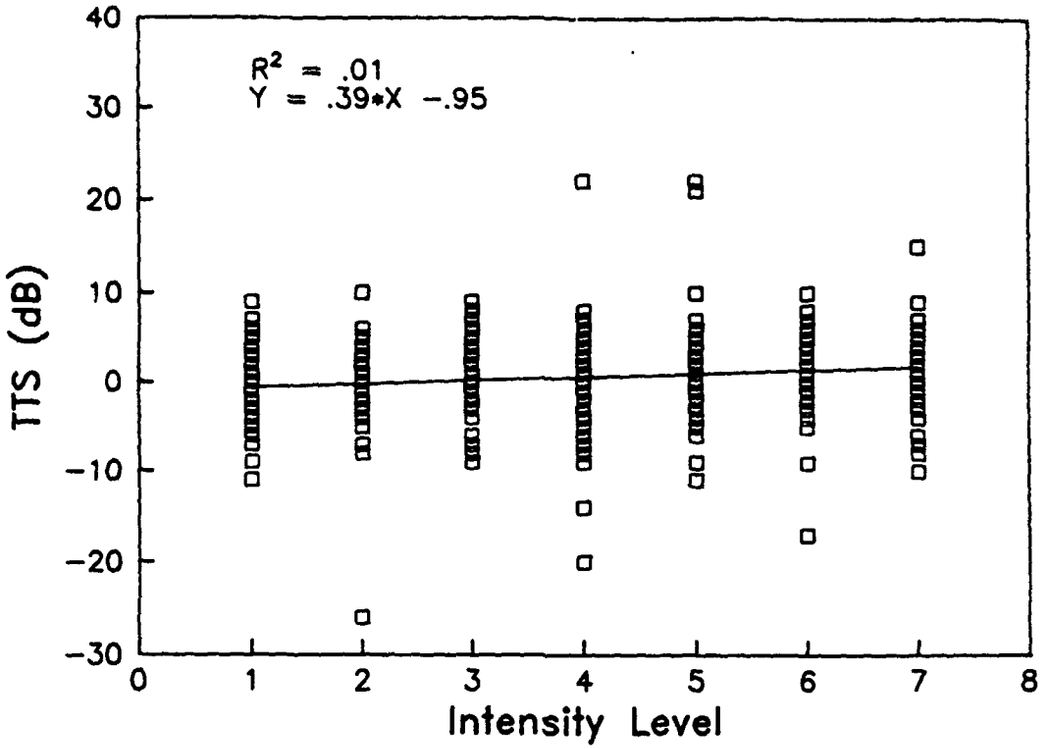


Figure III-16. Regression of TTS vs. intensity level, 3-m distance, 4000 Hz, right ear.

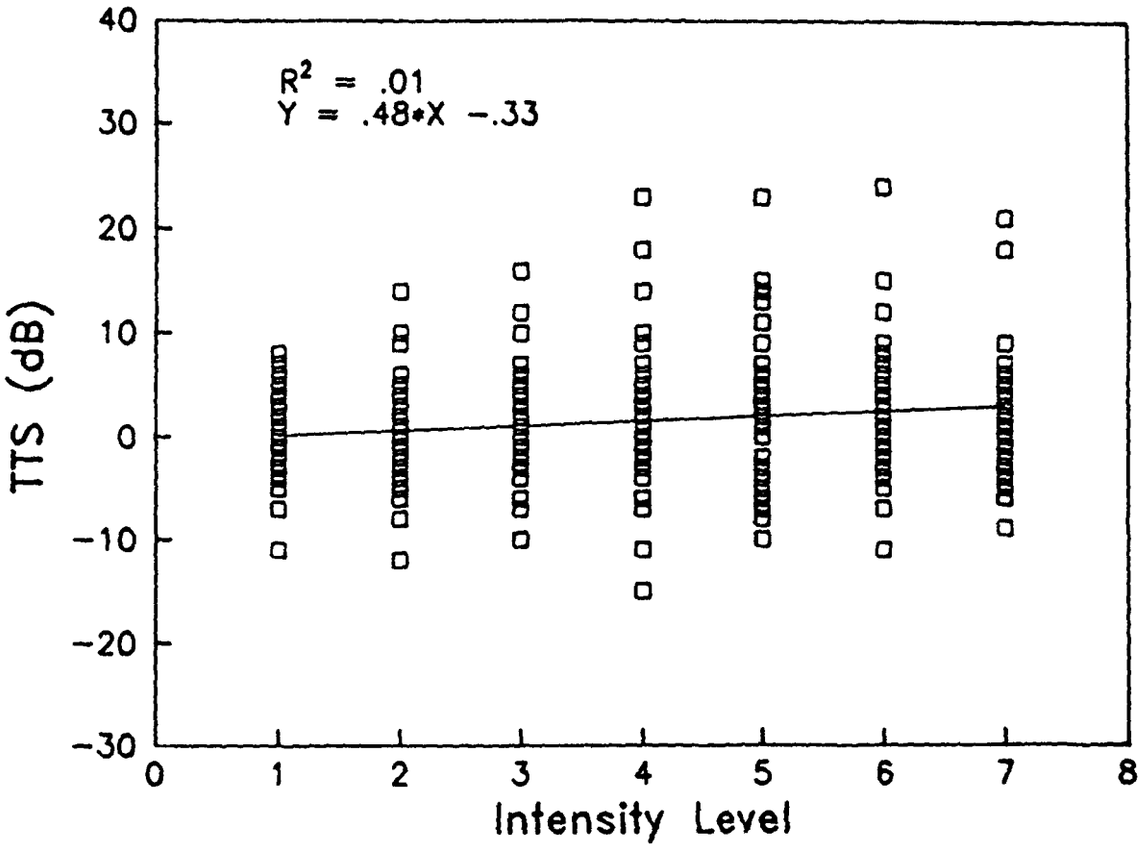


Figure III-17. Regression of TTS vs. intensity level, 3-m distance, 8000 Hz, right ear.

Level \ Number	6	12	25	50	100
7	1 7				
6	6 7	2 10	0 11	0 13	0 13
5	7 7	4 8	4 10	0 13	0 13
4	13 6	5 8	5 9	4 12	3 13
3	17 2	12 4	12 5	6 8	3 9
2	18 1	13 2	13 3	10 4	5 5
1	19 0	14 1	14 2	10 2	5 2

Figure III-18. Number of individuals passed (top number) and number of individuals showing an effect on hearing (bottom number) for each condition for perforated plug, 3-m distance, 19 subjects.

Number

Level	6	12	25	50	100
7	PAA1 PAA6 PAA7 PBD3 PAB5 1 PBC1 PAB3				
6	PAA1 PAA6 PAA7 PBD3 PAB5 7 PBC1 PAB3	PAA1 PAA6 PAA7 PAB6 PBD3 PAB4 PAB2 PAB5 5 PBC1 PAB3	PAA1 PAA6 PAA4 PAA7 PAB2 PAB4 PAB6 PBD3 PAB5 PBC1 PAB3	PAA1 PAA6 PAA4 PAA7 PAB2 PAB4 PAB6 PBD3 PBD2 PAB5 PBC3 PBC1 PAB3	PAA1 PAA6 PAA4 PAA7 PAB2 PAB4 PAB6 PBD3 PBD2 PAB5 PBC3 PBC1 PAB3
5	PAA1 PAA6 PAA7 PBD3 PAB5 9 PBC1 PAB3	PAA1 PAA6 PAB6 PBD3 PAA7 PAB5 2 PBC1 PAB3	PAA1 PAA6 PAA4 PAA7 PAB4 PAB6 PBD3 PAB5 6 PBC1 PAB3	PAA1 PAA6 PAA7 PAB4 PAB6 PBD3 PBD2 PAB5 PBC3 PBC1 PAB2 PAB3	PAA1 PAA6 PAA4 PAA7 PAB4 PAB6 PBD3 PBD2 PAB5 PBC3 PBC1 PAB2 PAB3
4	PAA1 PAA6 PBD3 [PAB5] 16 PBC1 PAB3	PAA1 PAA6 PAB6 PBD3 PAB5 1 PBC1 PAB3 PAA7	PAA1 PAA6 PAA4 PAB6 PBD3 PAB5 3 PBC1 PAB3 PAA7	PAA1 PAA6 PAA4 PAB6 PBD3 PBD2 PAB5 PBC3 PBC1 PAB4 [PAB2] 4 PAB3 PAA7	PAA1 PAA6 PAA4 PAB6 PBD3 PBD2 PAB5 PBC3 PBC1 PAB4 PAB2 PAB3 3 PAA7
3	PAA1 18 [PBC1] PAB3	PAA1 PBD3 8 PBC1 PAB3 [PAA7]	PAA1 PBD3 2 PBC 1 [PAB5] PAB3 PAA7	PAA1 PBC1 PBD3 PBD2 2 PAA7 PBC3 PAB5 [PAB4]	PAA1 PBC1 PBD3 PBD2 PBC3 PAB5 PAB4 PAB3 PAA7
2	18 PAB3	PBD3 5 [PBC1] PAB3	PBC1 PBD3 1 PAB3	PBC1 PBD3 PBD2 3 [PBC3] PAB3	PBC1 PBD3 PBD2 2 PBC3 PAB3
1	19 [PAB3]	2 PAB3	PBC1 2 PAB3	PBC1 PAB3	PBC1 PAB3

LEGEND:
Underlined or circled data means failure occurred from exposure to that condition.

Auditory Failure Extensions Number of Subjects Actually Exposed to Condition	PAA1 PAA6 PAA7 PBD3 DAB5 9 DBC1 DAB1	Nonauditory Failure Extension Conditional Failure Extensions

Figure III-19. Summary of failures for perforated plugs.

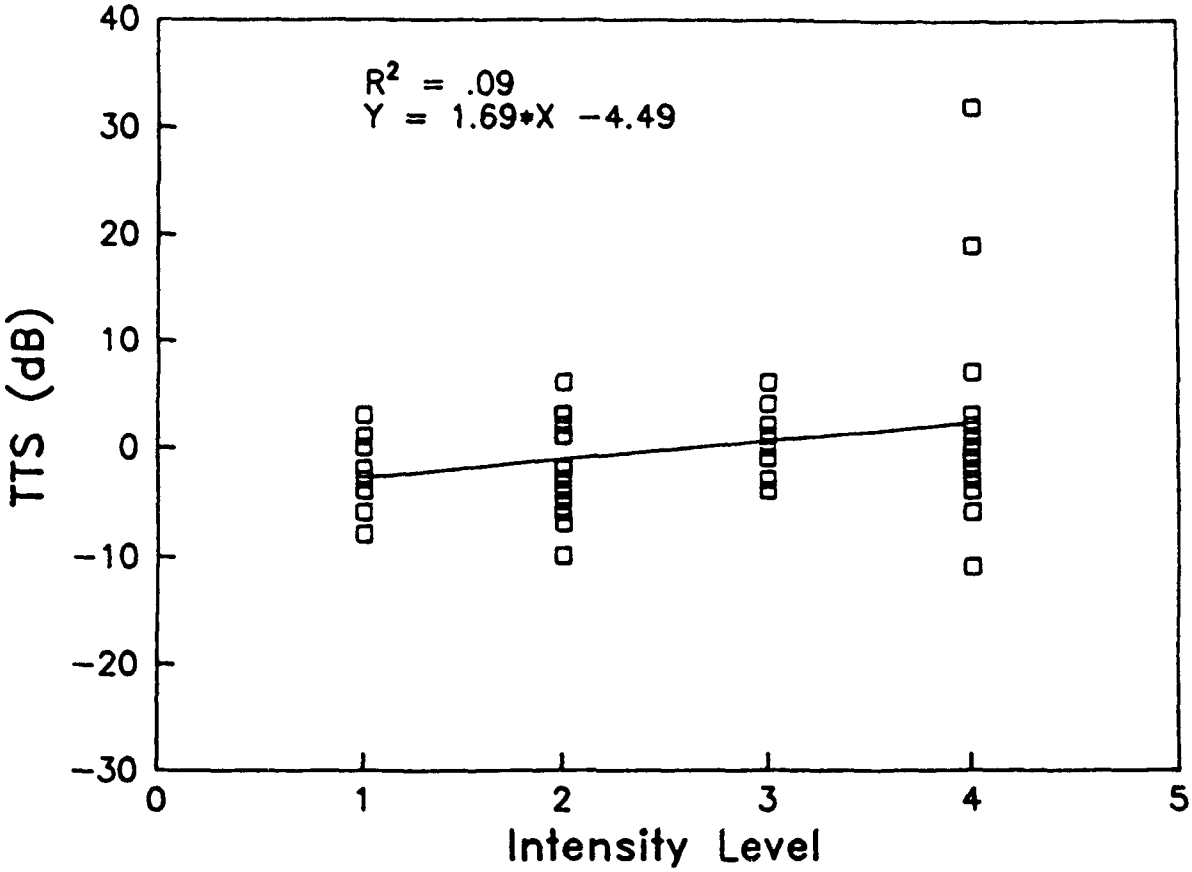


Figure III-20. Regression of TTS vs. intensity level, 3-m distance, perforated muff, 3000 Hz, right ear.

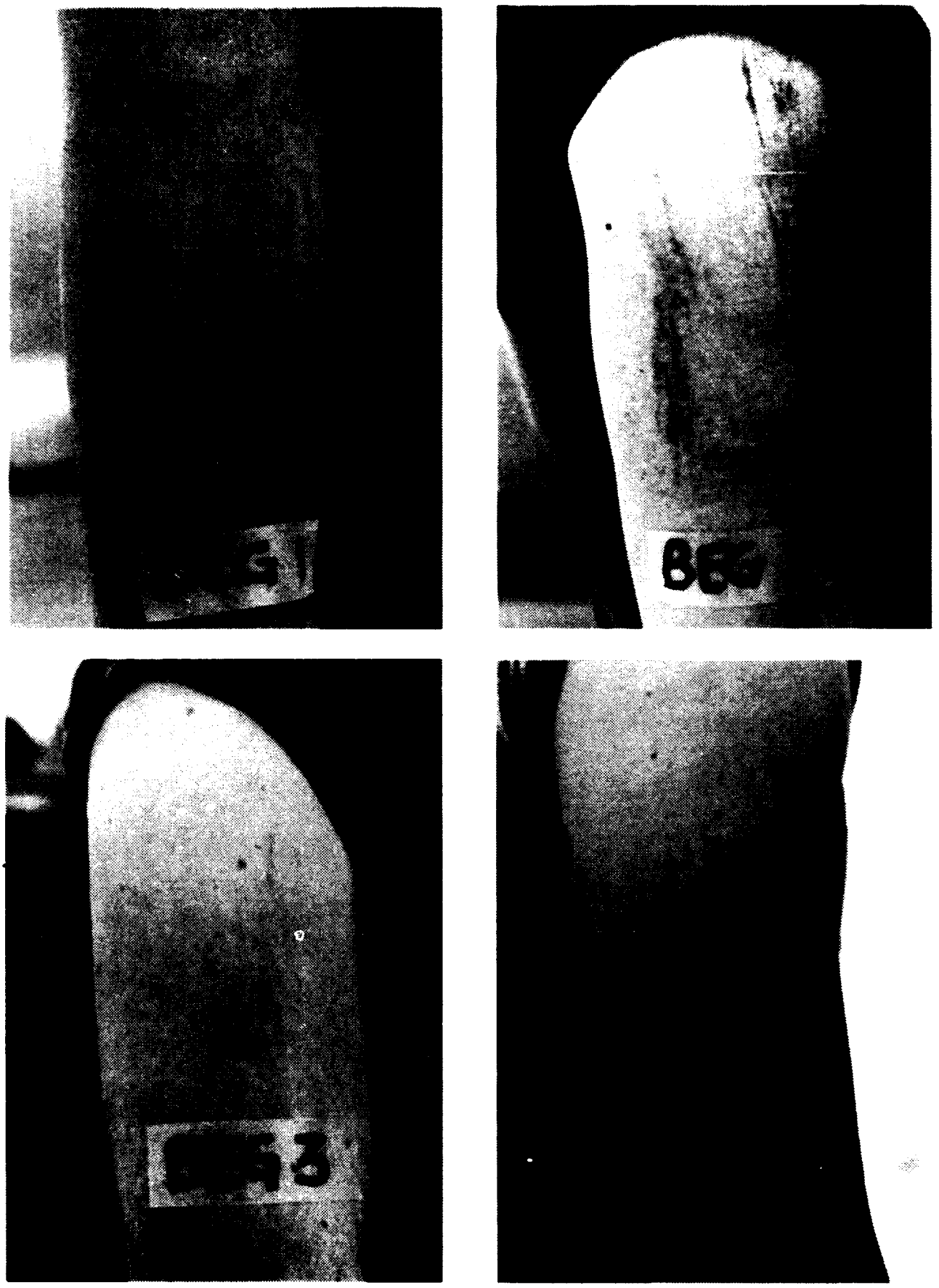


Figure III-21. Reddening of the arm facing the blast while wearing damp fatigue shirts.

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-22. Daily medical report prepared by physician assistant/nurse practitioner.

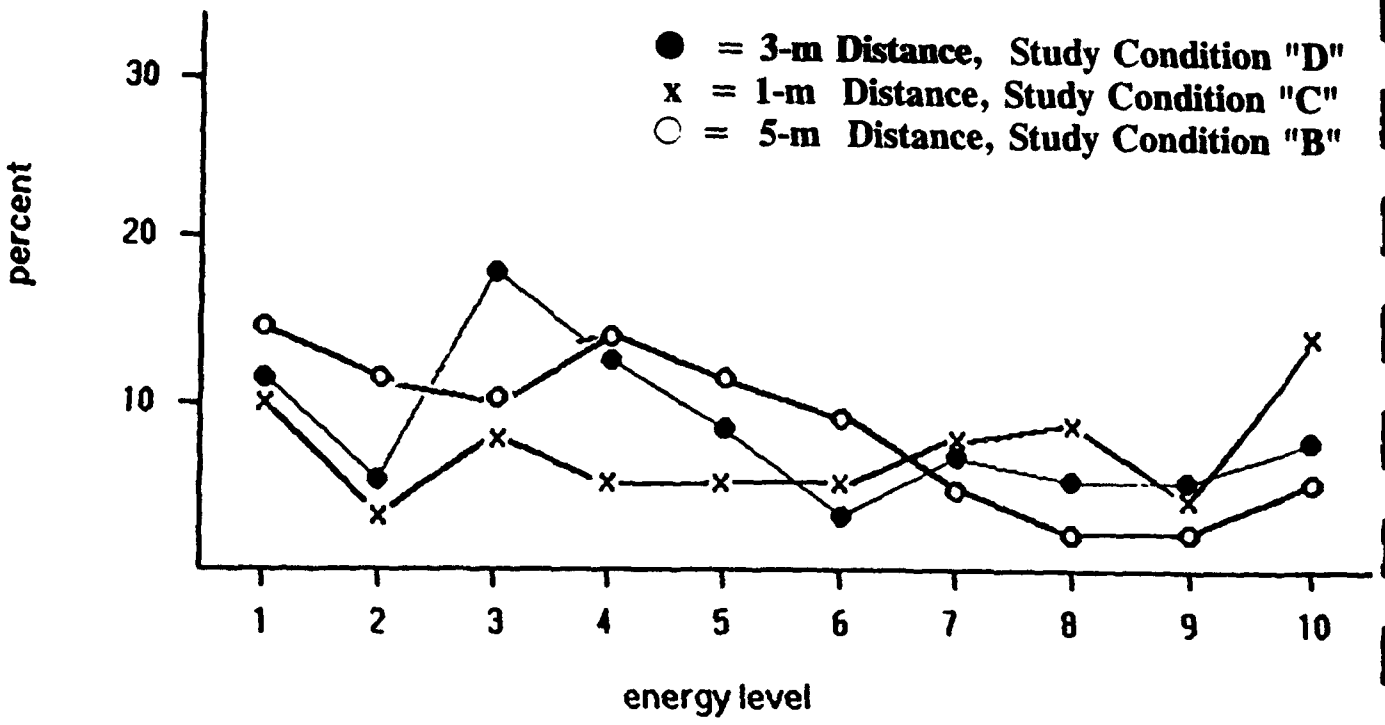


Figure III-23. Percent of time vs. energy level that subjects reported some problem with mouth or throat.

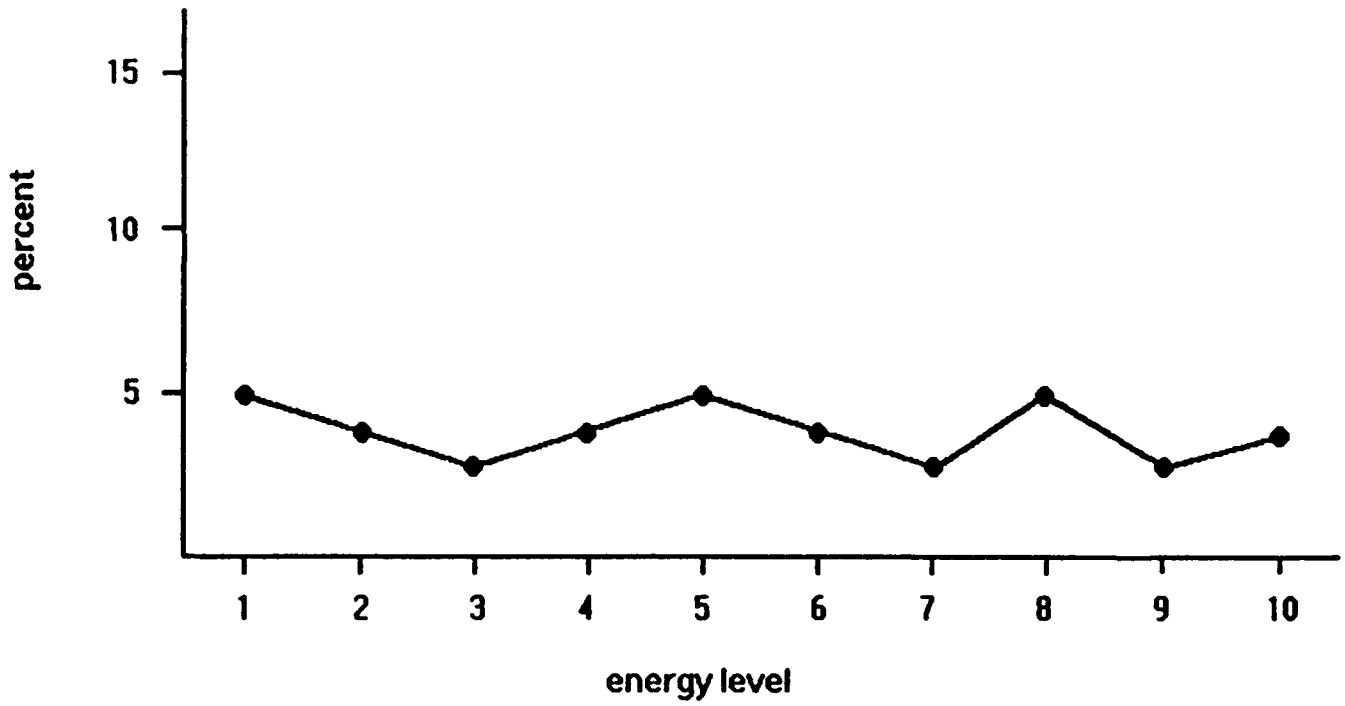


Figure III-24. Percent of time vs. energy level subjects reported some medical problem other than nose or mouth (throat). All study distances combined.

Level \ Number	6	12	25	50	100
7	16				
6	0	4	7	21	27
5	0	1	3	8	12
4	0	0	0	2	5
3	0	0	1	3	4
2	0	0	0	1	3
1	0	0	0	1	3

Number of X's

Please rank each block for acceptability to train using:

0 for ACCEPTABLE or o.k.

X for UNACCEPTABLE

Figure III-25. Final summary for "acceptability to train" questionnaire, acceptable/unacceptable response, 5-m distance. 47 subjects (45 subjects for level 7/6), November 1990 - June 1991.

Level	Number	6	12	25	50	100
7	5	9				
	4	11				
	3	1				
	2	8				
	1	15				
6	5	0	1	4	10	17
	4	1	2	5	9	6
	3	1	4	5	2	1
	2	5	8	11	18	18
	1	39	31	21	7	4
5	5	0	0	2	4	4
	4	1	1	1	7	10
	3	0	1	2	3	0
	2	2	6	7	12	16
	1	43	38	34	20	16
4	5	0	0	0	0	0
	4	0	1	1	5	6
	3	0	0	0	1	0
	2	0	2	5	6	16
	1	46	43	40	34	24
3	5	0	0	0	0	0
	4	0	0	0	2	2
	3	0	0	0	1	0
	2	0	1	4	7	15
	1	46	45	42	36	29
2	5	0	0	0	0	0
	4	0	0	0	2	2
	3	0	0	0	1	0
	2	0	0	1	5	12
	1	0	46	45	38	32
1	5	0	0	0	0	0
	4	0	0	0	2	2
	3	0	0	0	1	0
	2	0	0	0	4	11
	1	46	46	46	39	33

Please rank each block for acceptability to train using numbers 1-5 as follows:

1. Acceptable.
2. Acceptable but would not look forward to day in which exposure occurred.
3. No opinion or undecided.
4. Marginally acceptable but would be concerned each time I was exposed.
5. Unacceptable.

Figure III-26. Final summary for "acceptability to train" questionnaire showing finer breakdown response, 5-m distance, 46 subjects (44 for level 7), November 1990-June 1991.

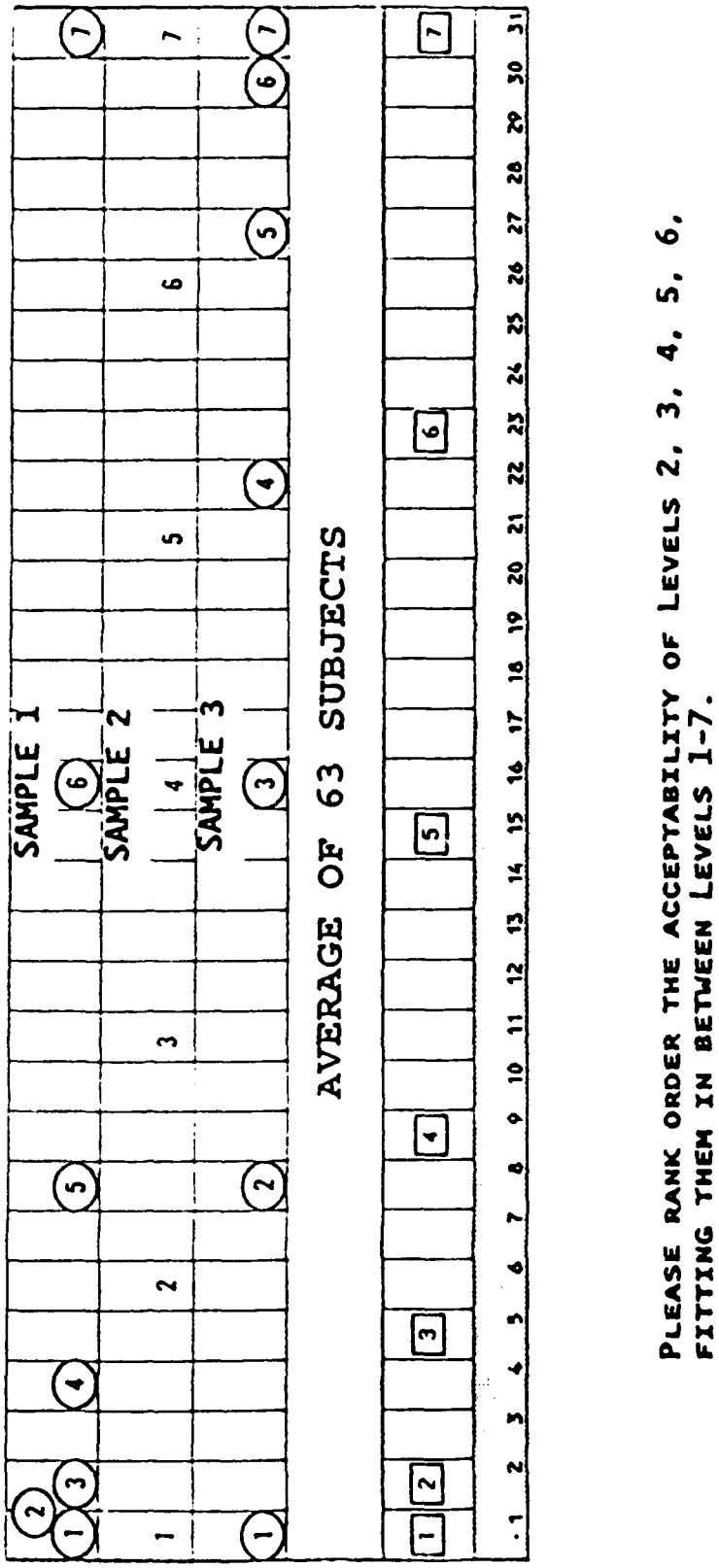


Figure III-27. Summary of rank ordering of acceptability for 5-m distance (63 subjects of study "B" and "M").

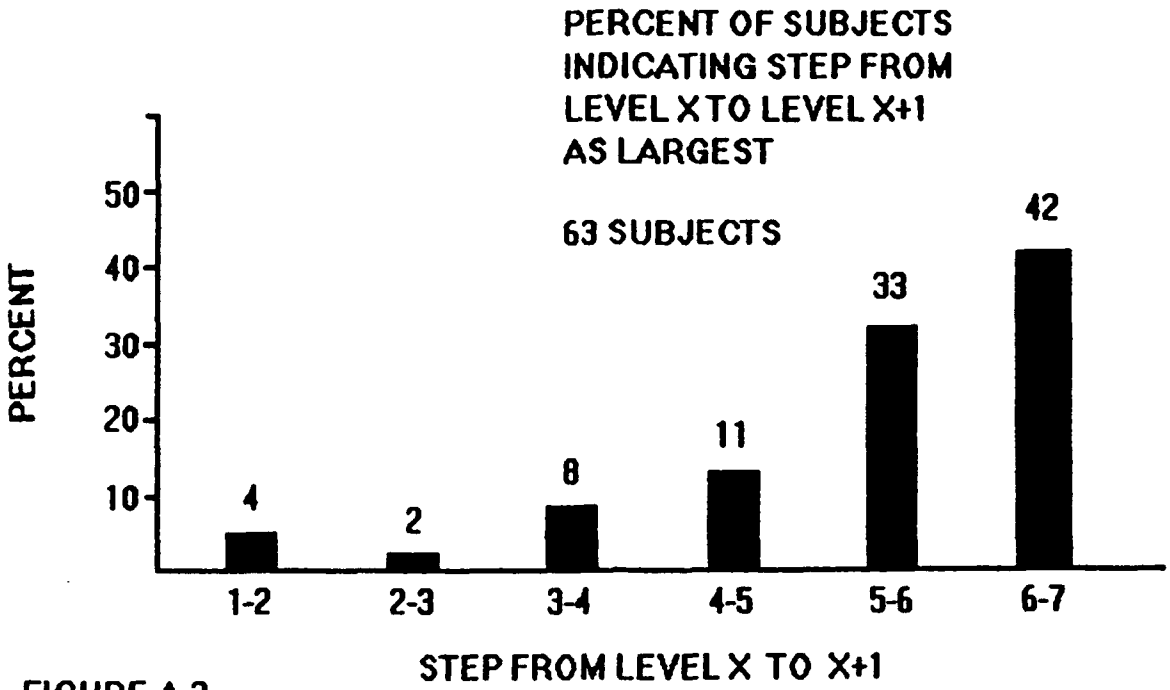


FIGURE A-3

Figure III-28. Percent of subjects which indicated the step from the one level to the next as the largest of the six steps. (Subjects from both study conditions "B" and "M," 5-m distance.)

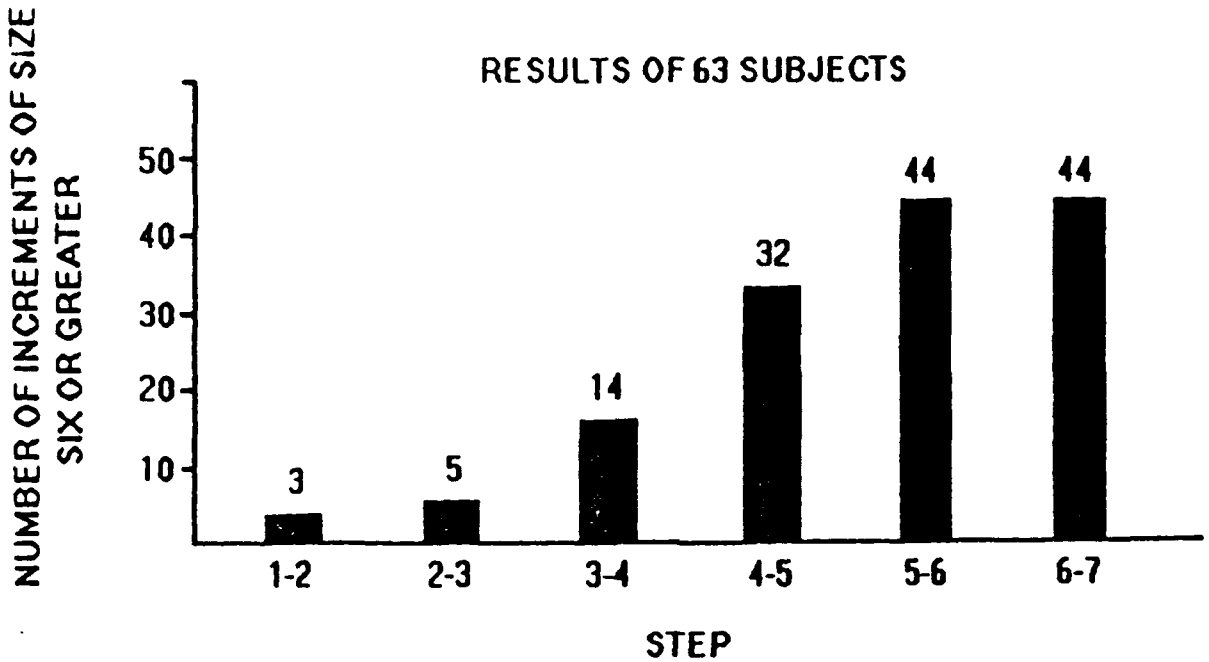


FIGURE A-4

Figure III-29. The number of times the size of the step as indicated on the horizontal axis was six units or more. The average number of units is four, 5-m distance.

BLAST OVERPRESSURE STUDY

LARYNGOSCOPIC EXAMINATION

Date: 8/23/91

Name: DAB-1

Social Security Number: 269-62-3784

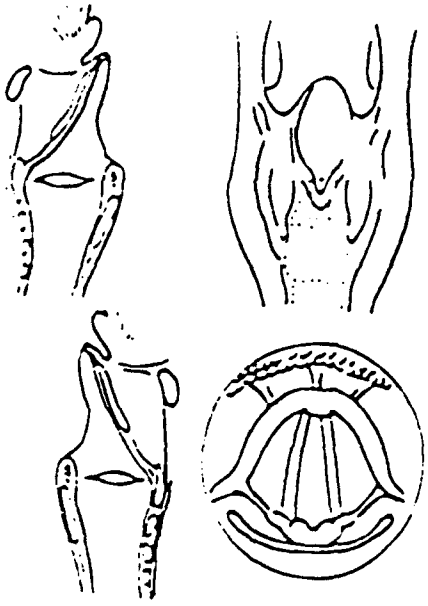
GENERAL NOSE AND THROAT ABNORMALITIES [2] (1-No; 2-Yes)

If "Yes," then describe ⊖ PETECHIAE AT RIGHT POSTERIOR SUPERIOR CHOANAE
⊖ PETECHIAE AT RIGHT POSTERIOR PALATOPHARYNGEUS MUSCLE

LARYNGEAL ABNORMALITIES [1] (1-No; 2-Yes, petechiae; 3-Yes, other laryngeal abnormality)

If "2-Yes, petechiae," then indicate location on figure:

If "3-Yes, other," then describe and indicate location on figure:



Signed: [signature] ESCUDERO

Figure III-30. Report of petechiae.

Level		Number 6	12	25	50	100
7	5	18				
	4	14				
	3	1				
	2	15				
	1	14				
6	5	2	3	7	15	22
	4	7	11	11	14	18
	3	1	0	0	3	2
	2	10	10	16	14	11
	1	42	37	26	12	5
5	5	0	0	1	10	9
	4	0	3	7	4	10
	3	2	1	1	0	6
	2	4	7	12	18	18
	1	56	50	39	26	15
4	5	0	0	0	0	1
	4	0	1	3	6	8
	3	1	1	1	1	2
	2	2	4	6	6	7
	1	59	55	50	45	40
3	5	0	0	0	0	0
	4	0	0	0	3	3
	3	0	1	1	1	2
	2	2	2	3	5	7
	1	60	58	56	49	46
2	5	0	0	0	0	0
	4	0	0	0	0	1
	3	0	0	1	1	2
	2	0	0	0	6	7
	1	62	61	59	51	48
1	5	0	0	0	0	0
	4	0	0	0	0	0
	3	0	0	0	0	1
	2	0	0	0	4	7
	1	62	61	60	54	50

Please rank each block for acceptability to train using numbers 1-5 as follows:

1. Acceptable.
2. Acceptable but would not look forward to day in which exposure occurred.
3. No opinion or undecided.
4. Marginally acceptable but would be concerned each time I was exposed.
5. Unacceptable.

Figure III-31. Grand summary - mortar distance.

Level	Number 6	12	25	50	100
7	X 23 0 35				
6	X 2 0 58	3 56	8 49	20 36	38 17
5	X 0 0 60	1 58	2 55	12 44	18 38
4	X 0 0 60	1 58	1 56	3 53	8 48
3	X 0 0 60	0 59	0 57	0 56	2 54
2	X 0 0 60	0 59	0 57	0 56	2 54
1	X 0 0 60	0 59	0 57	0 56	0 54

Please rank each block for acceptability to train using:

0 for ACCEPTABLE or o.k.

X for UNACCEPTABLE

Figure III-32. Summary of 60 subjects - mortar distance.

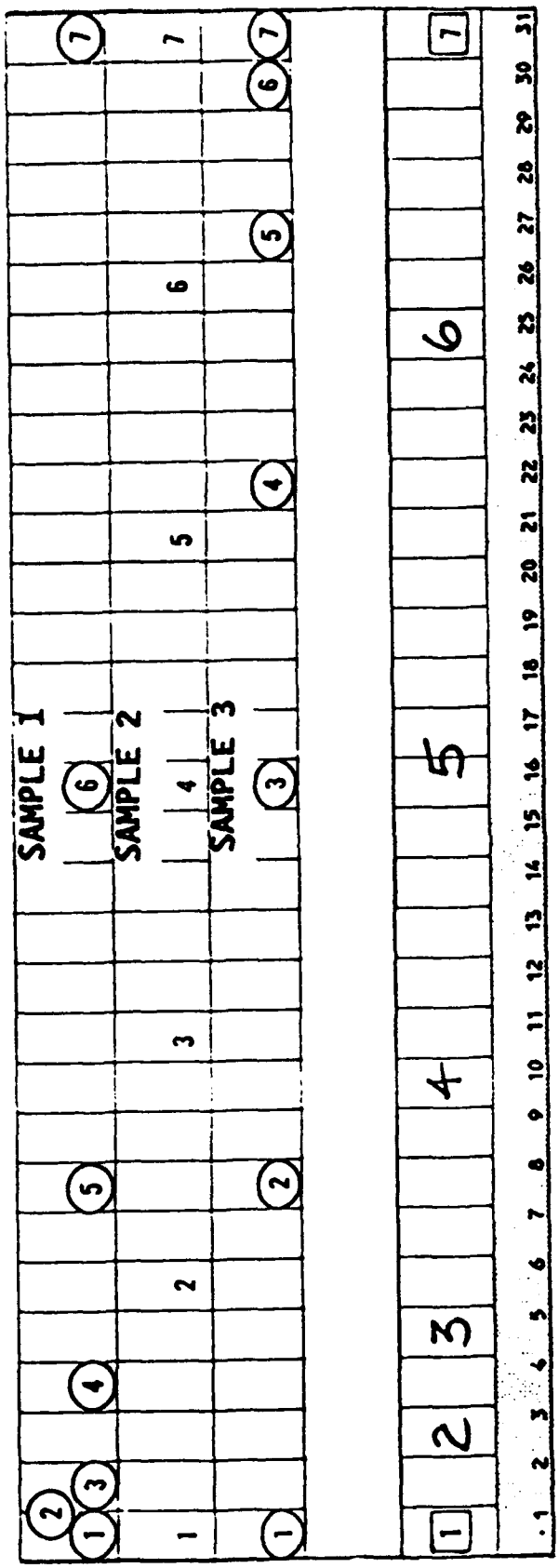


Figure III-33. Mortar distance summary.

Level	Number 6		12	25	50	100
7	5	15				
	4	9				
	3	4				
	2	11				
	1	18				
6	5	1	3	5	10	21
	4	3	4	7	11	12
	3	1	1	2	2	1
	2	11	14	14	17	14
	1	41	35	29	17	9
5	5	0	1	2	2	5
	4	2	2	5	14	13
	3	1	1	1	2	5
	2	9	10	10	8	14
	1	45	43	39	31	20
4	5	0	0	0	0	2
	4	0	0	1	3	3
	3	0	1	0	1	4
	2	6	8	10	14	13
	1	51	48	46	39	35
3	5	0	0	0	0	0
	4	0	0	0	0	0
	3	0	0	0	0	1
	2	1	1	3	7	9
	1	56	56	54	50	47
2	5	0	0	0	0	0
	4	0	0	0	0	0
	3	0	0	0	0	0
	2	1	1	1	3	5
	1	56	56	56	54	52
1	5	0	0	0	0	0
	4	0	0	0	0	0
	3	0	0	0	0	0
	2	0	1	1	1	3
	1	57	56	56	56	54

Please rank each block for acceptability to train using numbers 1-5 as follows:

1. Acceptable
2. Acceptable but would not lock forward to day in which exposure occurred.
3. No opinion or undecided.
4. Marginally acceptable but would be concerned each time I was exposed.
5 Unacceptable.

Figure III-34. Acceptability ranking for 3-m distance, 57 subjects.

Level \ Number	6	12	25	50	100
7	22				
6	0	3	7	15	29
5	0	2	3	6	20
4	0	0	0	0	6
3	0	0	0	0	3
2	0	0	0	0	3
1	0	0	0	0	3

Please rank each block for acceptability to train using:

0 for ACCEPTABLE or o.k.

X for UNACCEPTABLE

Figure III-35. Number of unacceptable ratings for 60 subjects, 3-m distance.

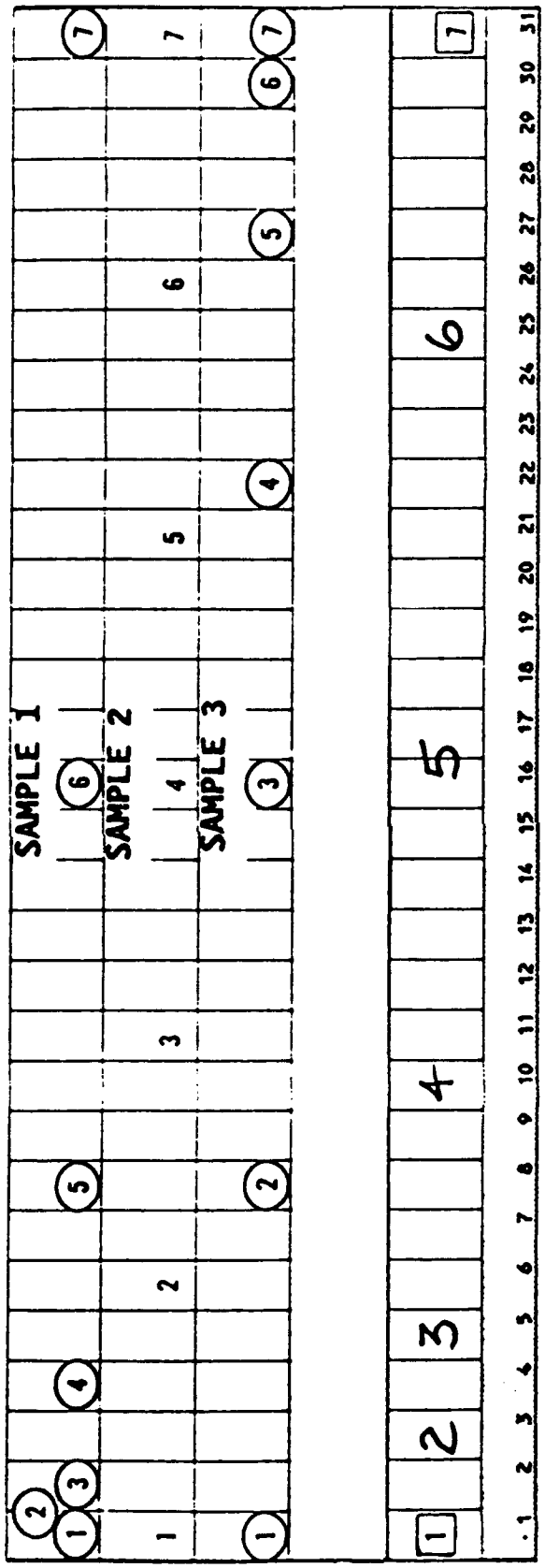


Figure III-36. Rank order of 3-m distance, 46 subjects.

Ear Redness Rating Report

Condition = Intensity @ Number Shots

		1@6		2@6		3@6		4@6		5@6		6@6		7@6	
		pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post
RIGHT	0	62	53	63	51	51	49	62	55	54	49	53	38	41	23
	1	4	15	5	10	10	18	5	12	13	16	11	24	6	21
	2				1	1	1						1	1	2
	3	2									3		1		2
LEFT	0	66	52	62	59	65	55	61	56	60	52	53	41	38	34
	1	2	15	5	9	3	13	6	11	7	14	10	21	9	11
	2		1	1	1								1		
	3										1	1	1	1	3

		12@6		25@6		50@6		100@6	
		pre	post	pre	post	pre	post	pre	post
RIGHT	0	50	27	51	31	32	23	31	21
	1	4	21	6	23	5	15	3	13
	2		4		2	1			
	3	1	3		1				
LEFT	0	44	36	34	32	30	21	31	26
	1	7	10	11	10	3	12	3	7
	2		2		2				1
	3	1	1	1	2				

Rating Scale

0 - No Redness
1 - slight injection of tympanic membrane
2 - Moderate injection of tympanic membrane
3 - Swelling or Hematoma

Figure III-37. Eardrum reddening rating report, 3-m distance.

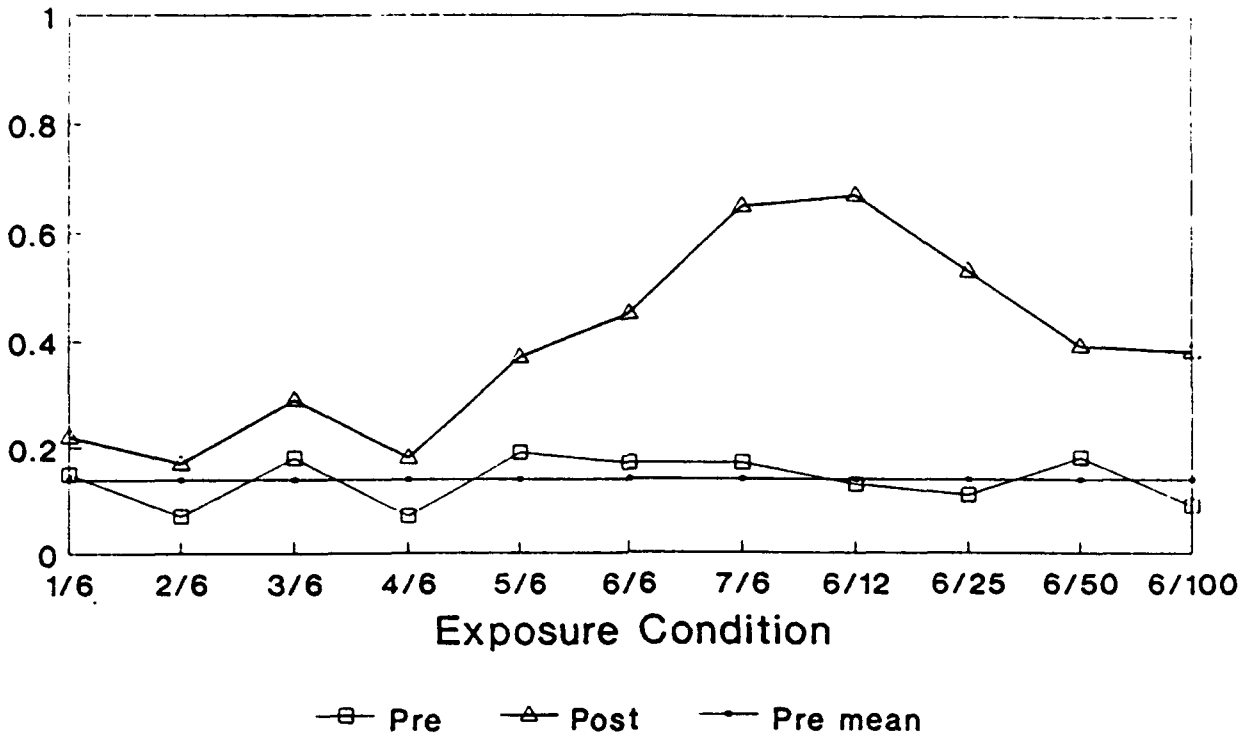


Figure III-38. Tympanic injection rating.

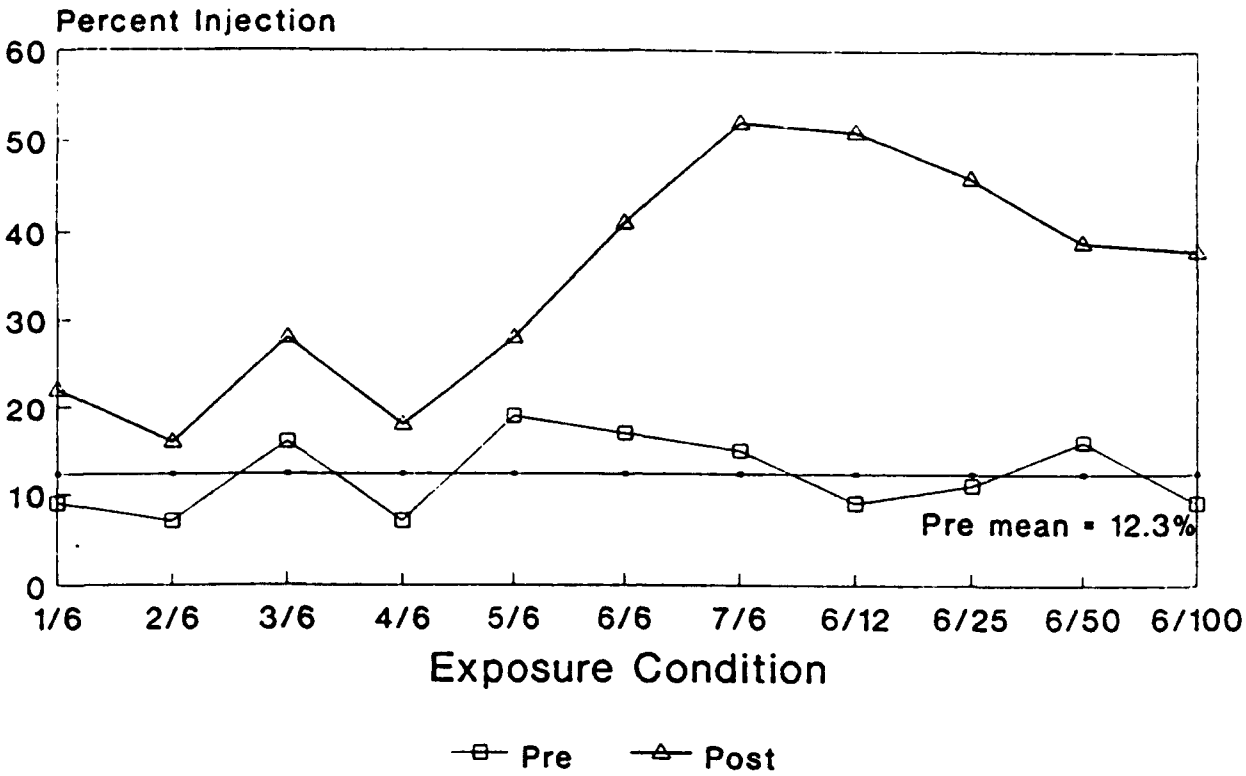


Figure III-39. Percent injection, right ear, 3-m distance.

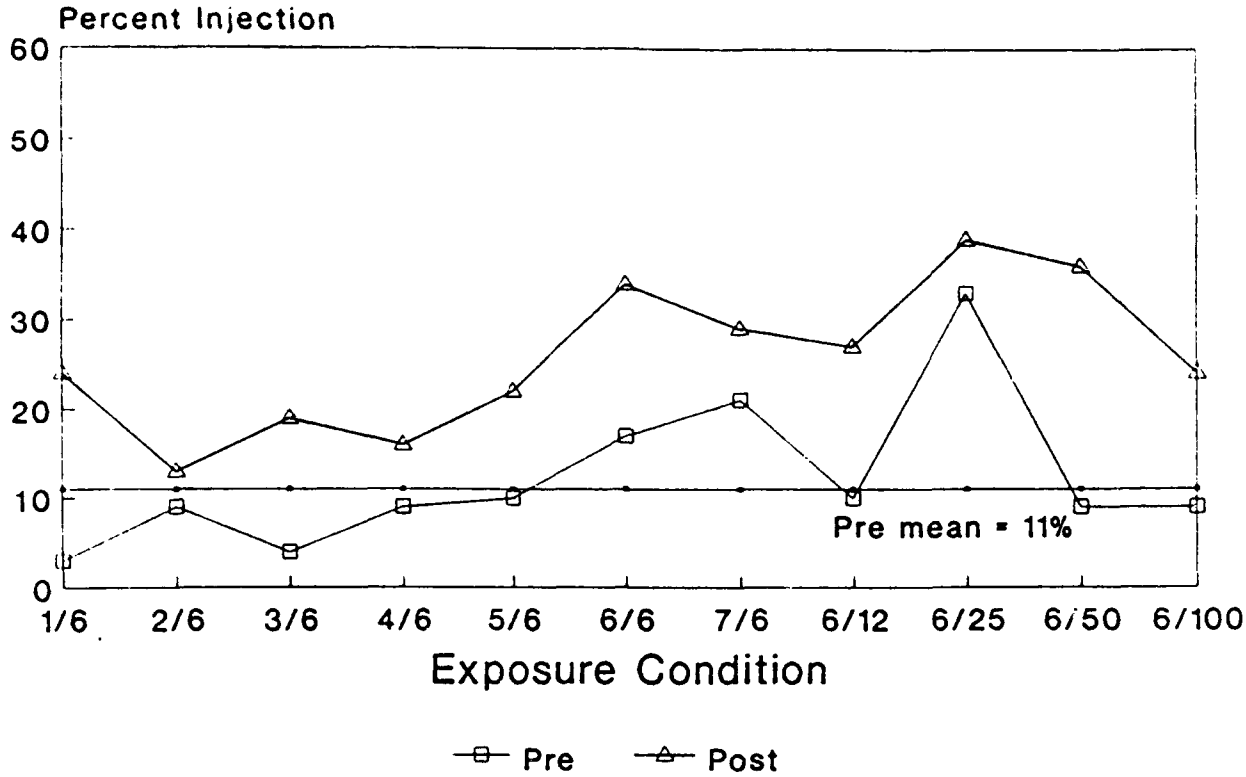


Figure III-40. Percent injection, left ear, 3-m distance.

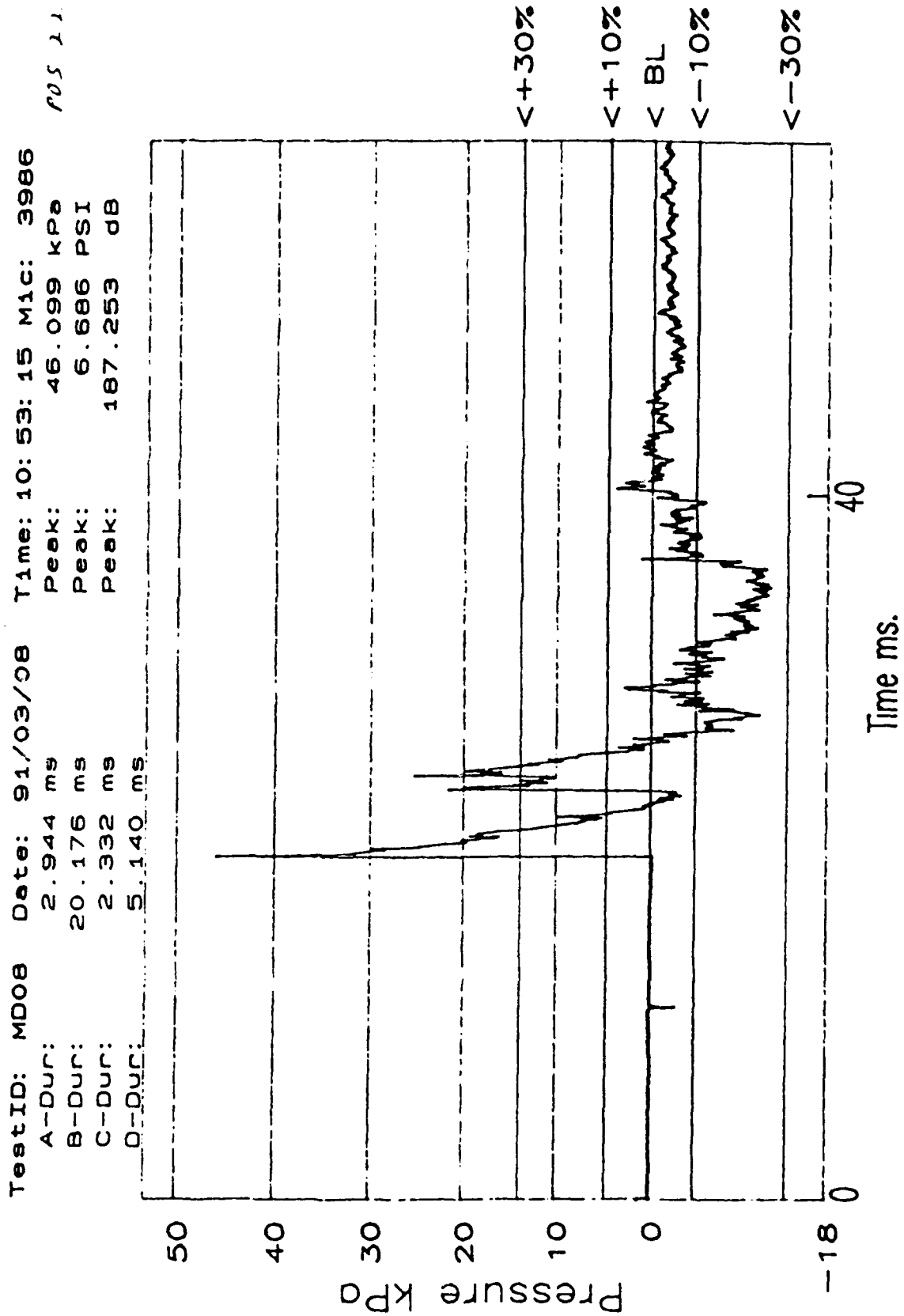


Figure III-41. Typical waveform of 5-m distance.

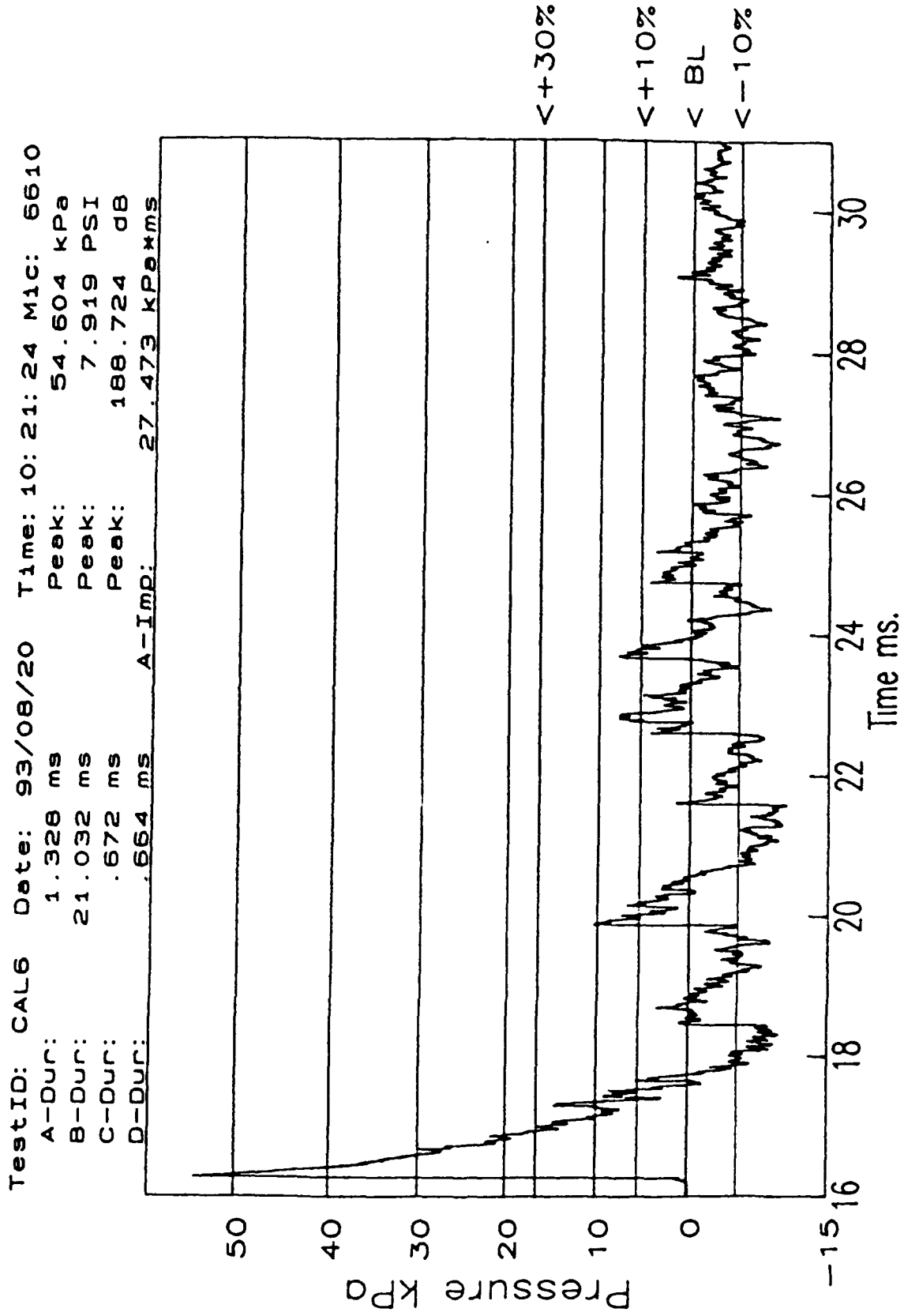


Figure III-42. Typical waveform of 3-m distance.

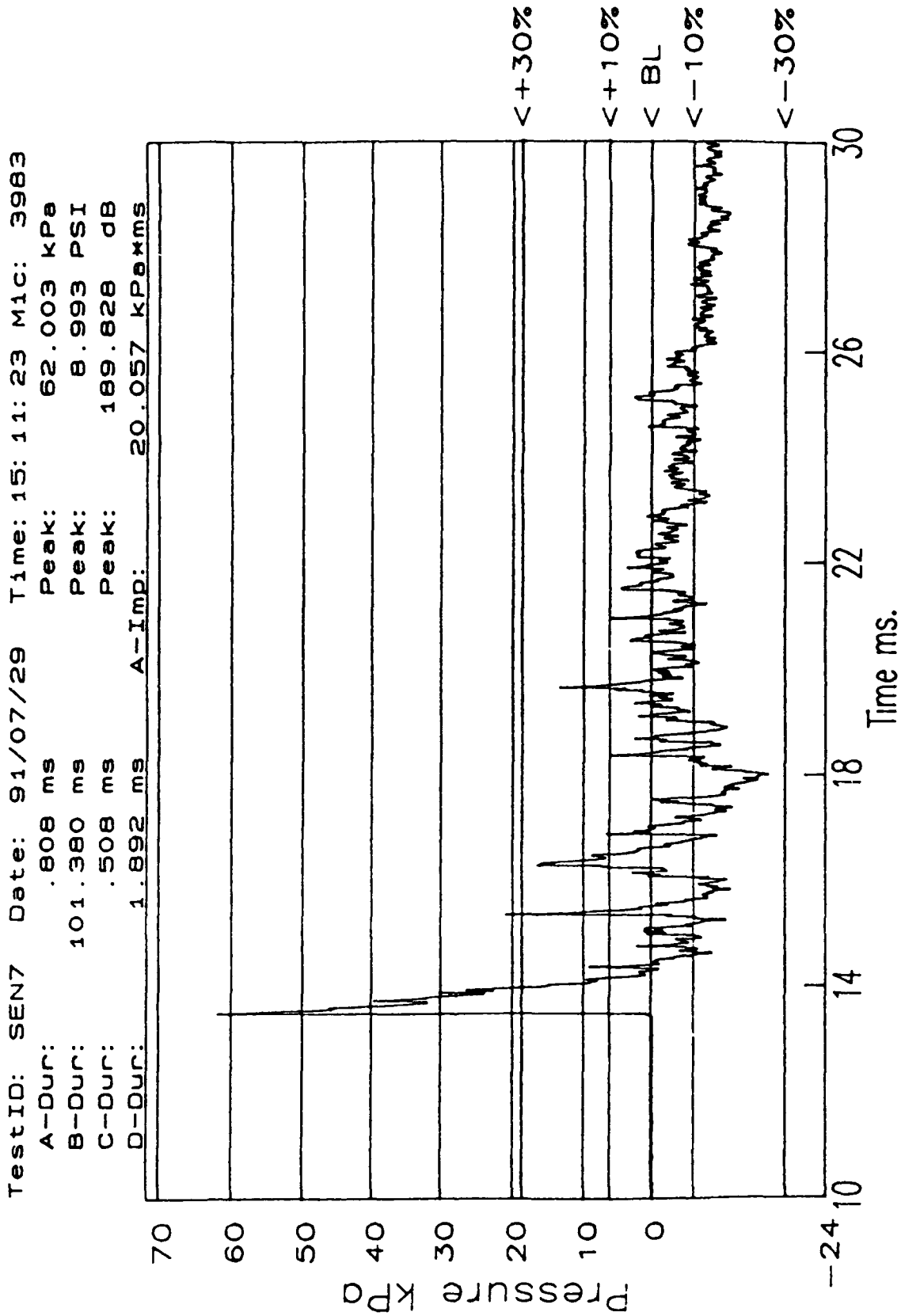


Figure III-43. Typical waveform of 1-m distance.

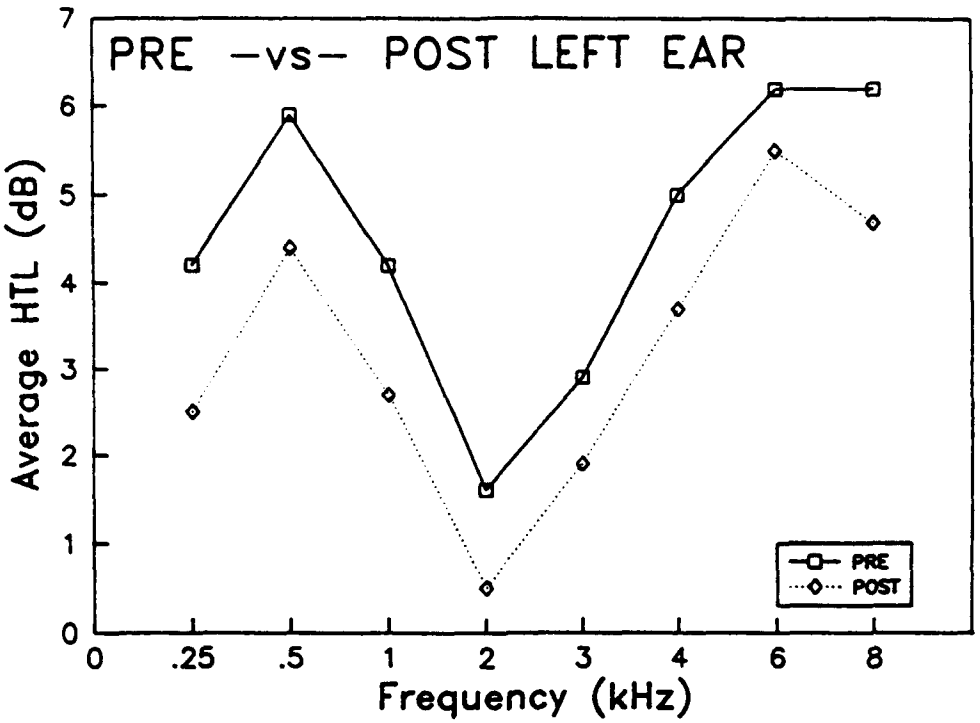


Figure III-44. Comparison of pre- and post-study hearing threshold levels of the non-test ear for 259 subjects.

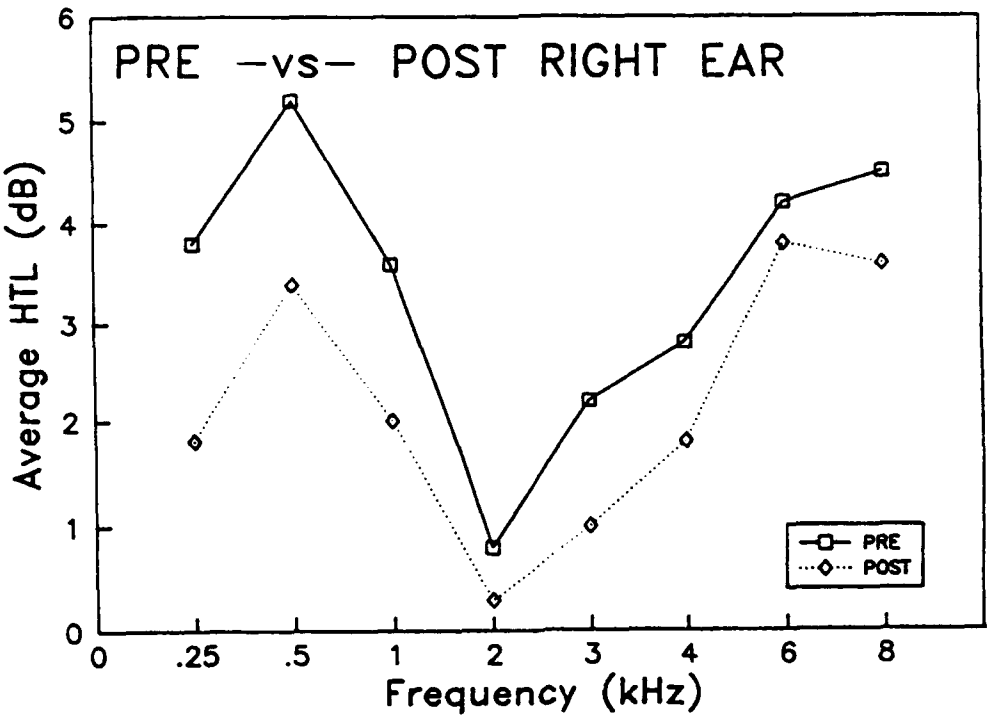


Figure III-45. Comparison of pre- and post-study hearing threshold levels of the test ear for 259 subjects.

IV. DISCUSSION

A. AUDITORY

1. Discussion of Each Distance

a. 5-m Distance, "B", Unmodified Muff

The results for the unmodified muff clearly show that the limits for exposure will be set by the non-auditory considerations. Referring to the matrix status shown in Figure III-3, it is impressive to note that not one audiometric failure occurred even though 39 subjects were exposed to the most energetic condition of 100 shots at 188 dB (Level 6). There were also 49 subjects who passed the condition with the highest SPL, i.e., six shots at 190 dB.

Since a failure in the matrix requires a shift of 25 dB, additional analysis was done to see if there was even a trend toward more TTS with increasing energy. Figure III-4 shows a regression of TTS vs level for 4000 Hz. Note that this frequency was selected as the one with a slope closest to 0. The fact that it is negative certainly reinforces that there isn't a clear trend for more TTS with increasing intensity. The slight improvement probably can be attributed to a slight continuance of a learning effect. However, most of the learning effect should have occurred by the numerous audiograms taken in order to establish a baseline.

b. 5-m Distance, "M", Modified Muff

The results of the 5-m distance using the modified muffs are best illustrated by the summary in Figure III-6. As with the standard unmodified muff, there were no auditory failures even at the condition with the highest peak SPL (6 shots at 190 dB). Thus, the peak sound pressure limit is set by non-auditory considerations even when a relatively poor hearing protector is used. On the other hand, at the most energetic condition of 100 shots at Level 6 (188 dB) there is a clear effect on hearing as illustrated by the results of Figure III-6. Table IV-1 was derived to evaluate the significance of the number of failures for the various conditions of the matrix.

The data in Table IV-1 will be used to determine whether or not a matrix condition is acceptable for various percents of the population to be protected from a TTS of more than 25 dB. The percentages of the population to be protected are 95% (<5% failure), 90%, and 80%. For 95% confidence, the table allows only 1 failure out of 47 subjects for protection of 90% of the population. Thus, 46 subjects must be considered to pass this condition. Using this methodology, Figures IV-1 through IV-3 summarizes for each of the three study distances that used the modified muff the matrix conditions that failed to protect for less than 95%, 90%, and 80% of the population. For example, using these values for the 5-m distance (Figure IV-1), condition 6/100 is closed out if the

goal is to protect over 90% of the population with this quality of hearing protection. Protecting 95% of the population eliminates condition 6/12 and the corresponding energy conditions 5/25, 4/50, and 3/100,as well as any higher condition. It should be remembered that this nice relation with energy comes from the results of just one subject.

The alternate method of looking at the data is doing a regression analysis of TTS vs peak SPL for the 6-shot condition. The results shown in Table III-7 indicate that the audiometric frequency with the greatest positive slope was 6000 Hz. Even so, the slope is quite small and mean TTS would be predicted to grow less than 0.06 dB per a decibel increase in peak level (Figure III-7). In any case, a coefficient of correlation of 0.09 is not significant.

TABLE IV-1

FOR 95% CONFIDENCE
LESS THAN 20%, 10%, or 5% OF POPULATION WILL HAVE
TTS MORE THAN 25 dB

No. of Failures	Number of Passes Needed	Total Completed
80% of Population Pass (20% Fail)		
0	15	15
1	23	24
2	28	30
3	36	39
4	41	45
5	49	54
6	54	60
7	62	69
90% of Population Pass (10% Fail)		
0	30	30
1	46	47
2	58	60
3	74	77
95% of Population Pass (5% Fail)		
0	60	60
1	93	94

c. 1-m Distance, "D", Modified Muff

The final matrix for this study distance is shown as Figure III-11. There are definitely a relatively large number of audiometric failures. Certainly, for this type of waveform associated with this distance, and for this type of hearing protection, audiometric considerations dictate the safety limits. As opposed to the earlier study distances, the selection of allowable vs unallowable conditions is more difficult. Figure IV-2 shows the matrix cells in which the exposures would be unacceptable depending on whether or not more than 95%, 90%, or 80% of the population would be protected against 25 dB of TTS with 95% confidence. Note that most of the matrix is blocked out if less than a 5% audiometric failure rate is desired (>95% of population protected). Figure III-13 shows a regression of TTS vs level that almost exactly matches the results of the "M" study condition. Again, the frequency with the greatest slope was at 6000 Hz and, again, R was not statistically significant at the $\pm.05$ level.

d. 3-m Distance, "C", Modified Muff

The final matrix (Figure III-14) for the 3-m distance is not unlike the 1-m distance. With the degraded performance of this hearing protector, the auditory instead of non-auditory considerations set the upper limit of exposure. Condition 6/100 was closed out during the testing with 11 failures, so not all subjects even had an opportunity to experience that condition. The conditions that would provide unacceptable exposure to 95%, 90%, and 80% of the population are indicated in Figure IV-3. For protection of 90% of the population, all Level 6 conditions as well as conditions 5/50 and 5/100 are unacceptable. For 95% of the population, the drop is generally one energy condition (condition 4/25 is only exception).

A regression of TTS vs. level is shown in Figures III-16 and III-17. The greatest slope was at 8000 Hz. Still this is only a 0.16 dB change in mean TTS for each decibel change in level. Furthermore, an R of 0.1 is still not statistically signficant. These results only emphasize the approach of looking at significant TTS in individuals. The resulting matrix shown in Figure III-14 is certainly more informative.

e. 3-m Distance, "P", Perforated Plugs

Even though there were only 19 subjects that started the study, the number of failures is impressive. The perforated plugs were just not providing protection (as determined by TTS) that was provided by the modified muff. The results (Figure III-18) show increasing failures with number of exposures. Because of the few subjects, nothing can be concluded about the protection of 95% or 90% of the population. But protection of 80% of the population is estimated to occur only for condition 1/6. Perhaps

the best comparison is with the 80% protection level of the modified muff for the 3-m distance. Condition 5/100 is still acceptable for the modified muff. Look at the difference between conditions 5/100 and 1/6. Condition 5/100 is four energy steps (12 dB) up in level from Level 1 and eight energy steps (24 dB) from Level 1 at 6 shots. It is impressive that there is such a difference in performance between these two protectors.

The use of TTS vs. Level was done only for the first four levels. This is shown in Figure III-20. The largest slope occurred at 3000 Hz, but from Table III-7, there were relatively large slopes for all frequencies. However, R was not significant at any frequency; again, emphasizing the benefit of looking at each audiometric failure as an individual event.

f. No-Countdown

As stated earlier, aside from the one conditional failure there was little difference with respect to TTS between the countdown and no-countdown exposure. The one conditional failure can be discounted at this time because the protocol was not set up to verify such a failure by further exposure. The purpose of the no-countdown addendum was to check for large differences, not differences that might only become significant by using 50 to 60 subjects.

2. Comparison of Study Distances

For the modified muff, three different distances were used, representing three different waveforms. Perhaps the best approach for analyzing the results of these distances is to compare each matrix. Figure IV-4 compares the three distances with protection of 95%, 90%, and 80% of the population. A symbol in the box for an exposure condition signifies that the condition is unacceptable for the criteria represented by the symbol. In Figure IV-4, the duration of the impulse is ignored. Using only peak level, it is surprising how well the data from the different distances compare. If the data are plotted against energy level, as done in Figure IV-5, a slightly different picture emerges. Use of energy seems to be a slightly worse predictor.

There is one clear difference between the three distances that can be seen by Table III-1. For the 1-m distance, the PI stopped exposure before the normal completion of the matrix for five subjects with auditory failures and two subjects for non-auditory reasons. The reason for the early termination was abnormal behavior of the resulting TTS. Either the TTS was too high, did not recover within 24 hr, or had a pattern of growth. These cases all happened at Level 5 (190 dB) or higher. It is interesting to note that this problem did not occur for the 3 m (C) and 5-m (M) distances. For this reason, it may be advisable to not expose soldiers to peak levels of 190 dB and above.

B. NON-AUDITORY

1. Discussion of Each Distance

a. 5-m Distance, Modified and Unmodified Muffs

Because of the longer duration, the exposure at this distance caused more discernable movement of the chest. There were two cases (out of 12 subjects) of petechiae on the larynx-pharynx that occurred. Other than these two incidents, there were no incidents of injury. The several cases of the reddening of the upper right arm all occurred when the sleeves of the army fatigue uniform were wet. This problem can easily be avoided by either a heavier dress (such as the field jacket) or going bare-armed.

b. 1-m Distance, Modified Muff

The short duration of this distance was compensated by the much larger peak level. The exposure feels more like a blow to the side of the head than a squeeze of the chest of the 5-m distance. There were three cases of non-auditory failures out of 65 subjects. The first failure, the case of petechiae on the larynx, was expected. The loosening of the impacted wisdom tooth was surprising, but certainly not a serious problem. The hematoma on the right ear of subject DBD6 after the 193-dB exposure (Level 6) perhaps shows that levels above 190 dB probably should be avoided. While not counted as failures, the subjects who had rib injuries from touch football again illustrate that these very high peak levels might only be acceptable to soldiers in good physical shape.

c. 3-m Distance, Modified Muff

The duration and peak levels were in between those of the 1-m and 5-m distances. This subjectively felt more like a slap to the head and a hug to the chest. But, whatever the blast wave of this distance felt like, there were non-auditory failures out of 68 subjects. There was only the one subject that elected to quit because the blast waves bothered his otherwise sore throat.

2. Comparison of Non-Auditory Effects at Different Distances

In general, there were not enough non-auditory failures at any distance to state positively that one study condition is of more concern than any other condition. The mortar distance did have three cases of non-auditory failure. The three failures that occurred were all different. Thus, there is no clear cause and effect relationship established.

The three principal investigators were exposed to each of the three study distances. There was no clear consensus among the

three investigators that subjectively one distance was worse than another.

C. PROPOSED SAFE LEVELS

Combining the results of all three distances there appears to be reasonable levels per number of exposures as determined by percent to be protected. These levels are depicted in Figure IV-6. It is especially interesting to note that the line protecting 90% of the population (10% not protected) follows the simple curves that is proportional to energy. Perhaps the best way to predict the curve of level vs number for protecting 95% of the population is to use the curve for 90% and change it to protect 95% by a fixed reduction in peak level. In the case of Figure IV-6, a decrease of approximately 6 dB of peak level would do this.

However, it should be remembered that these results are based on a hearing protector that was intentionally degraded by putting holes in the seal. For the unmodified muffs or any other reasonably good hearing protector, these curves should be shifted up by 6 dB or more.

D. QUESTIONNAIRES

1. 5-m distance, Unmodified Muff

Unfortunately, the use of a questionnaire to determine the acceptability to train at the various exposure conditions was not implemented until November 1990. However, this is where the exit questionnaire is of some help. Notice that the answers to THE question (intensity of the blast) were similar for the 5-m distance using both the modified "M" and unmodified "B" muffs. Likewise, the breakdown of the answers to the rest of the questions on the exit questionnaire were similar. For this reason, we recommend the results of the questionnaire for study condition "B" be used for the "M" study condition. This distance is discussed in the next section.

2. 5-m Distance, Modified Muff

The questionnaires were implemented part way through the study. Only 6 of 59 subjects completed the questionnaire. The results show an increasing dislike for the more energetic conditions. However, the peak level becomes a more important factor once Level 7 is reached.

There is a substantial difference between the subjects' adverse opinion of condition 7/6 vs the general acceptance of the same energy condition of 6/12. In fact, condition 6/50 seems to best match the results from condition 7/6. These results are generally the same whether acceptability is ranked on a 1-5 scale or on a simple Yes/No question. The principal investigator believes

that most subjects were conscientious in their effort to fill out these questionnaires. The Yes/No questionnaire was given first and the 1-5 rating type of questionnaire was given second. Almost always the individual's response was consistent between these two types of questionnaires. It should be recognized that these results should only be used as indicators of dislike of a particular condition not as an absolute indicator as to whether or not the subjects would indeed train. In fact, several subjects who marked condition 6/100 as unacceptable stated that they would work under that exposure condition but only "if their sergeant made them" or "if they had to." These comments apply to all the study conditions.

3. 1-m Distance, Modified Muff

The results from the mortar distance show a greater dislike of more energetic exposure conditions than was seen for the 5-m distance. This especially shows up for condition 6/100. In general, there is about a 3-dB step difference between the 5-m and 1-m study distance.

4. 3-m Distance, Modified Muff

The 3-m distance showed a subject acceptability that falls in between the 1-m and 5-m distance. Otherwise, the pattern seen at the other distances is also seen at this distance.

5. 3-m Distance, Perforated Plug

Because there were only 19 subjects and because no subjects were even exposed to the conditions 6/25 and greater and 5/50 and greater, the questionnaire was not provided. In addition, there was such a strong dislike of the perforated plug by some of the subjects that they would not want to wear it under any conditions, much less train with it.

6. Comparison of All Distances

The consistent pattern of non-acceptability among all the study distances is useful. First, there is always a strong change from condition 7/6 to condition 6/6. Almost none of the subjects found Level 6 at 6 shots objectionable. Since Level 7 is probably not a reasonable exposure level to be allowed for both auditory and non-auditory reasons, the acceptability of this exposure becomes a non-issue. The rank ordering charts for study conditions M, D, and C do not add much to this conclusion except that the step from Level 6 to Level 7 is not shown to be any larger than the step from 6 to 6. This, of course, is inconsistent with the clear change in acceptablity between Levels 6 and 7. Perhaps this result shows the sensitivity of the results to the question asked. For the conditions with increasing number of shots, auditory failure considerations nicely eliminate the conditions for all three study distanc-

es that the subjects found the most objectionable. Because of this fact, we would not expect acceptability of training for properly motivated and informed soldiers to be a problem at conditions in which the ear can be properly protected by single hearing protection.

E. OTHER ISSUES

1. General

During the testing, there were several efforts started and then stopped. Either these efforts did not bear any important results and/or were too costly in terms of time and effort. A discussion of these efforts follow:

a. MMPI

This psychological test battery was started with the first subjects and eventually dropped with the first group of 1-m distance. Many of the volunteer subjects strongly objected to this test and admitted to not carefully answering the questions. The tests were all sent to Ft Rucker. It is our belief that it is very unlikely that the tests can provide any useful insights as to the stress of the subjects during the blast exposures. The exit questionnaires should be a better indicator.

b. Asteriods

The subjects had a video game called asteroids available to them at the control building. The subjects could play this game during their idle time. For groups MD, ME, and MF, pre- and post-blast scores were kept. However, this video game is not well suited for a performance test as extra "ships" become available upon obtaining certain scores. This would cause very long playing times for some subjects which would then conflict with the audiometric testing programs. Since the audiometric testing had priority, this idea was dropped. While not analyzed in detail, results from 17 subjects would indicate the same scores after blasting than before.

c. Otoacoustic Emissions

The equipment for these tests arrived in December 1992. Training was started and in the summer of 1993 some tests were performed. The test schedules required for the audiometry did conflict with doing otoacoustic emission testing on but a few subjects. This equipment was obtained for determining the feasibility of use in future studies. There was one informative case in which it was successfully used. Subject PBD-3 had a lingering TTS that recovered only after 16 days. The on-site audiologist COR performed a series of otaoacoustic emission tests during the recovery phase. In general, the loss shown by the emissions tests paralled

those of the threshold test. Both showed recovery of the subject's hearing at the same time.

d. Earmuff Movement

At the highest levels of each study distance, the RACAL earmuff can move away from the head sufficiently to break the seal. This is not considered to be a problem for a single blast as the shock front for a freefield wave is gone by the time the seal breaks (approximately 15 msec after the incident wave strikes the muff). For a sequence of shocks (such as a reverberant situation or a battery of howitzer firings in the freefield) this would not be true. Thus, all the data at the extremely high levels, Levels 6 and 7, rely on single freefield waves.

At Level 5 and lower, earmuff movement is not considered a problem. Thus, at the levels that are most likely to be acceptable from an auditory standpoint (Level 5 and lower), this consideration can be neglected.

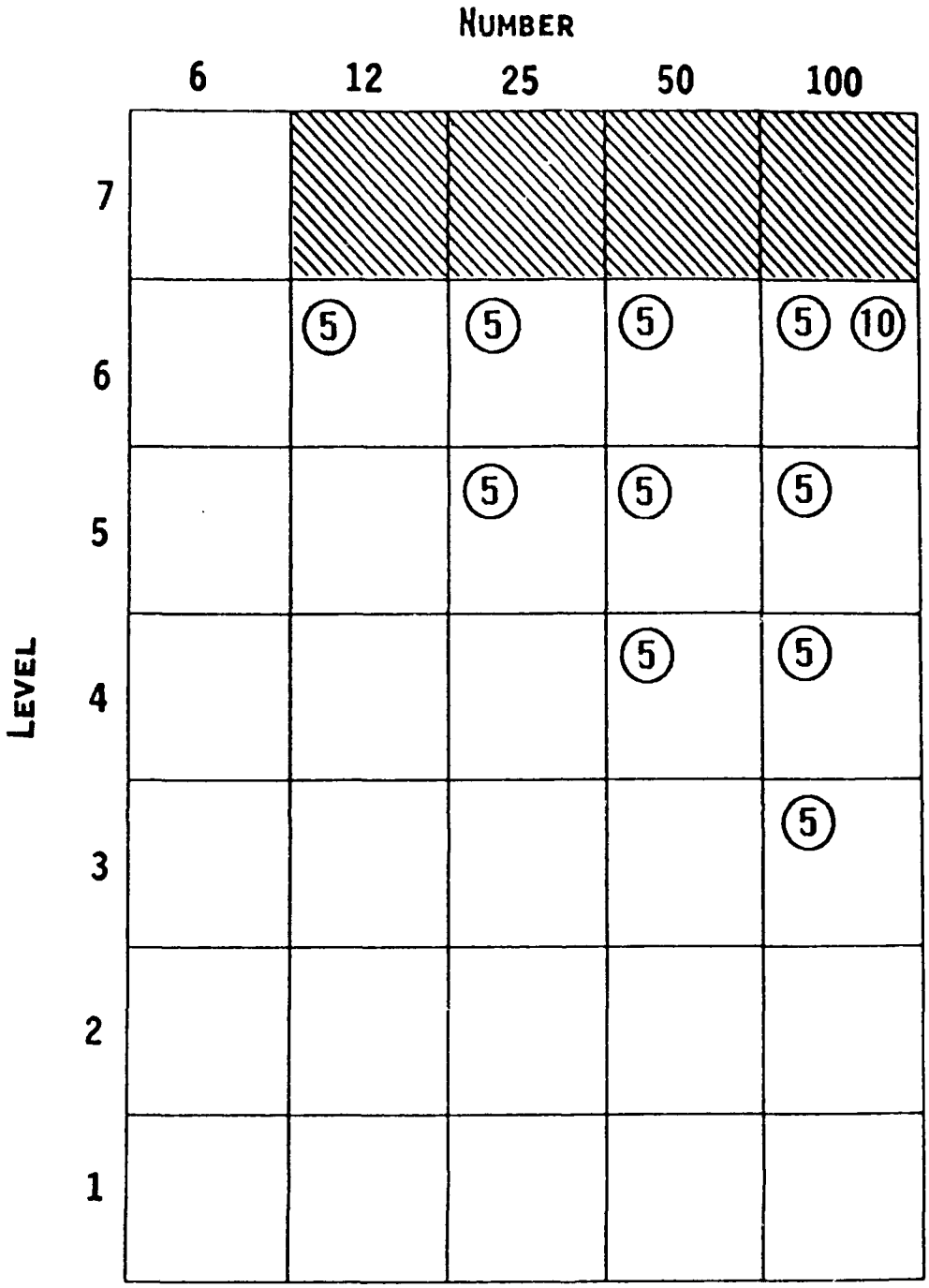


Figure IV-1. Conditions Rejected for Protection of 95%, 90%, and 80% of the Population, 5-m Distance, Modified Muff.

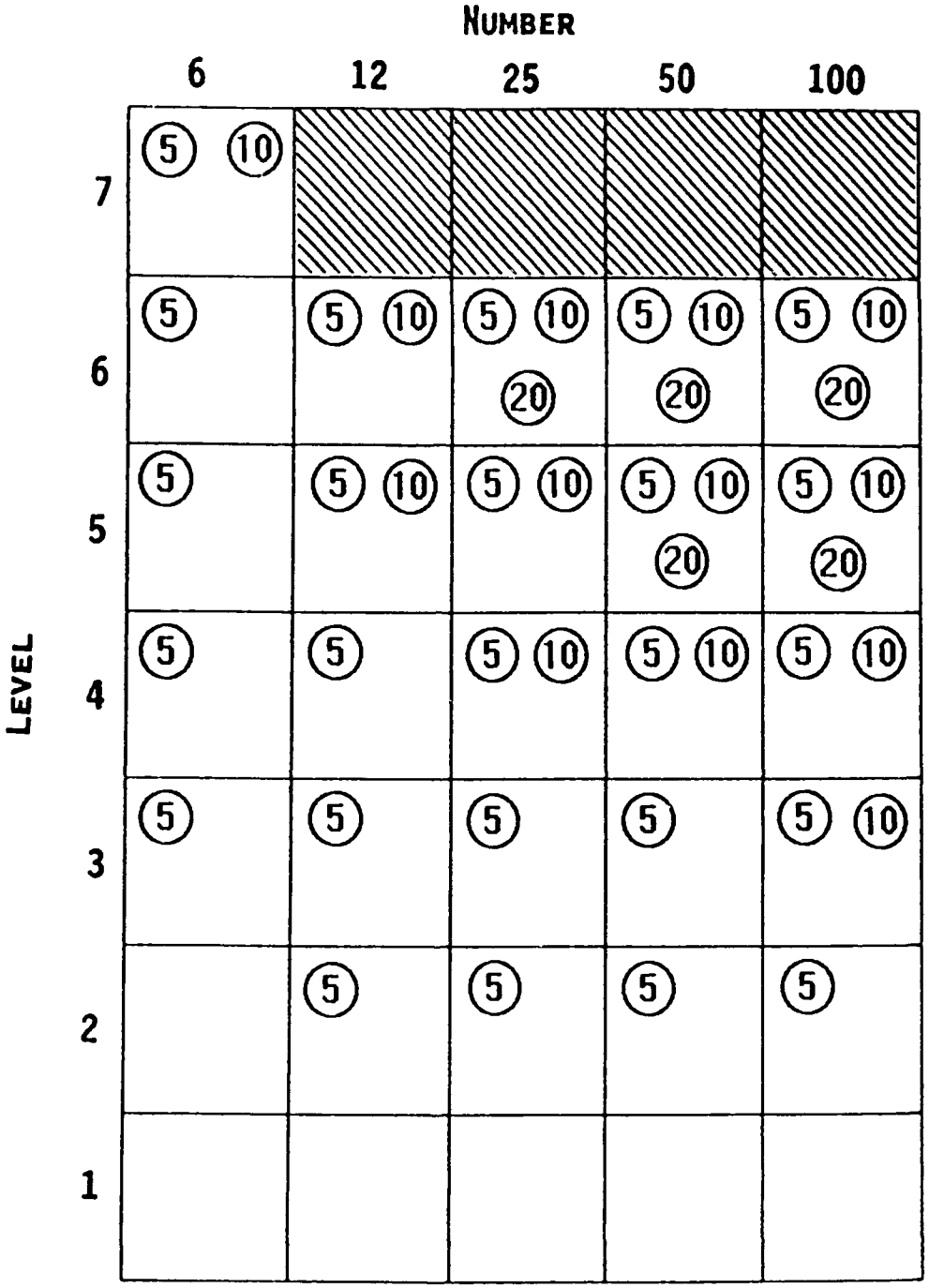


Figure IV-2. Conditions Rejected for Protection of 95%, 90%, and 80% of the Population, 1-m Distance, Modified Muff.

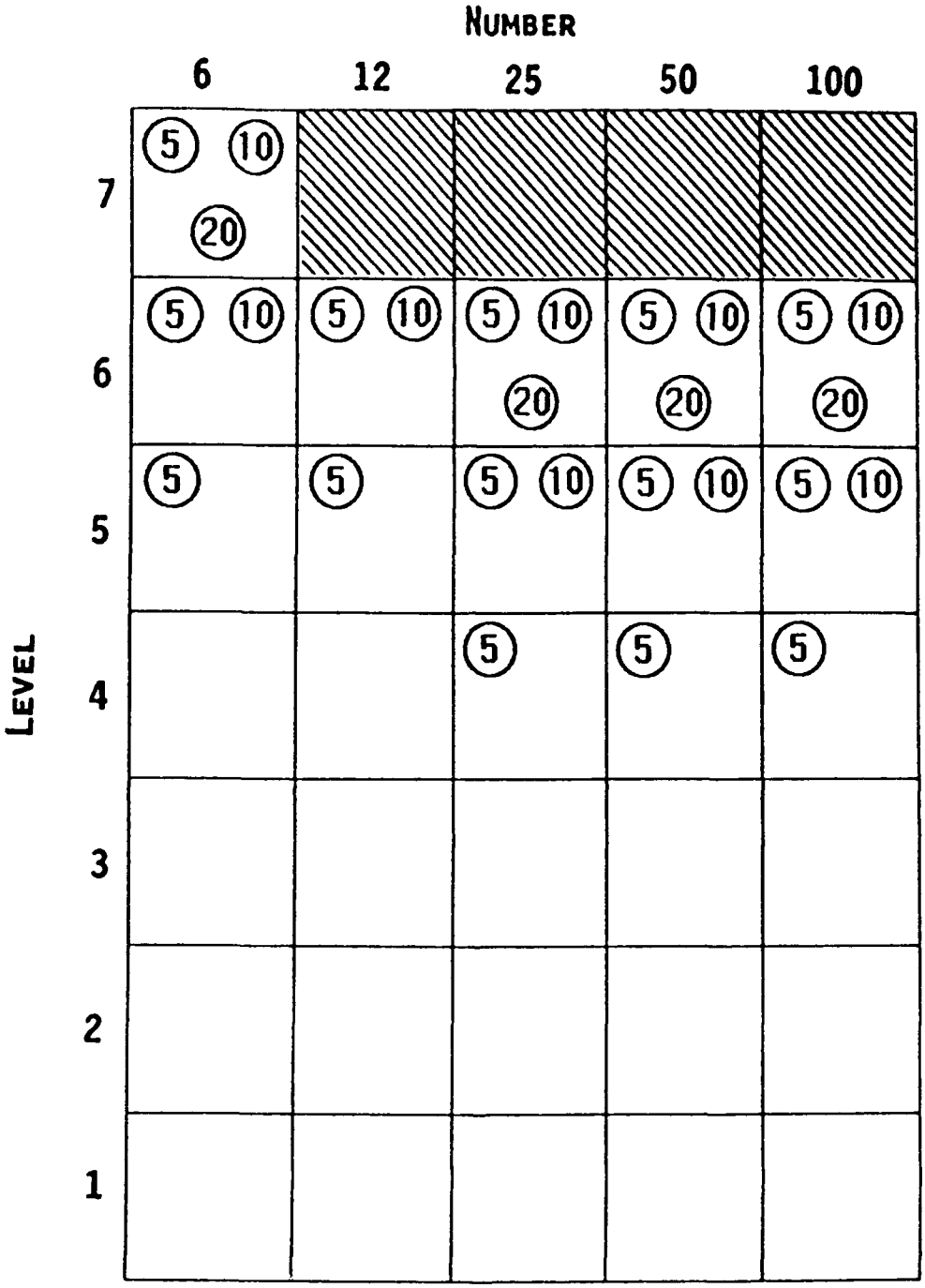


Figure IV-3. Conditions Rejected for Protection of 95%, 90%, and 80% of the Population, 3-m Distance, Modified Muff.

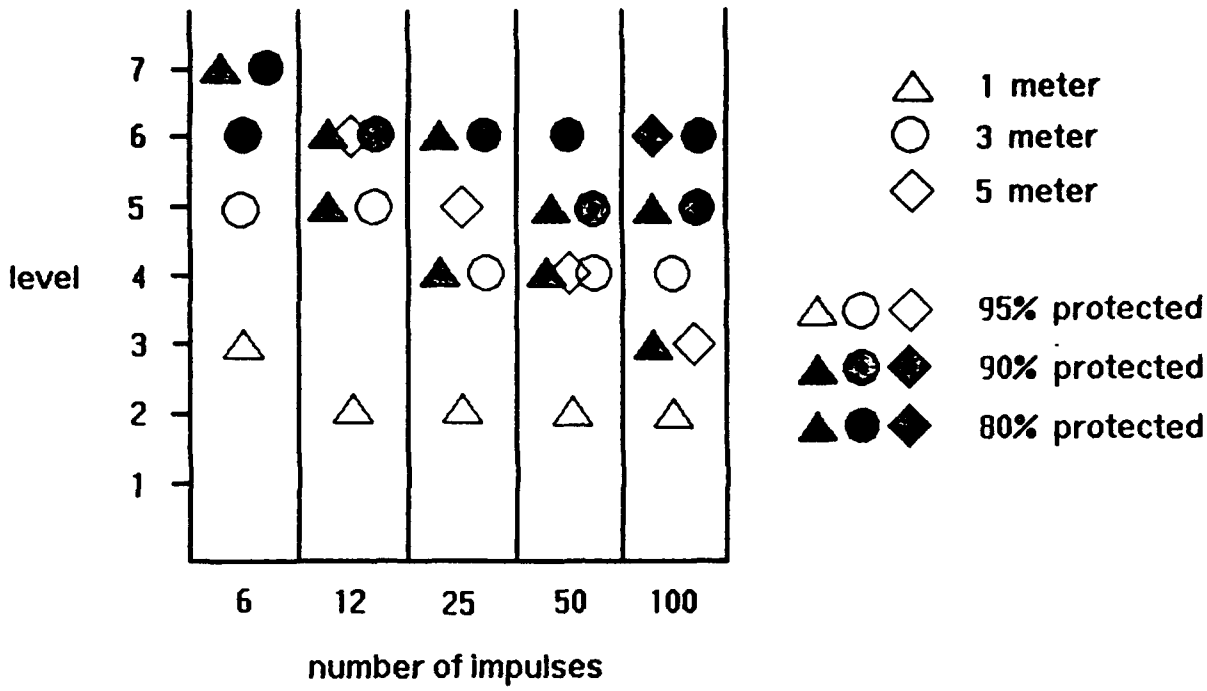


Figure IV-4. Comparison of Acceptability of the Three Distances vs Peak SPL for the Modified Muff.

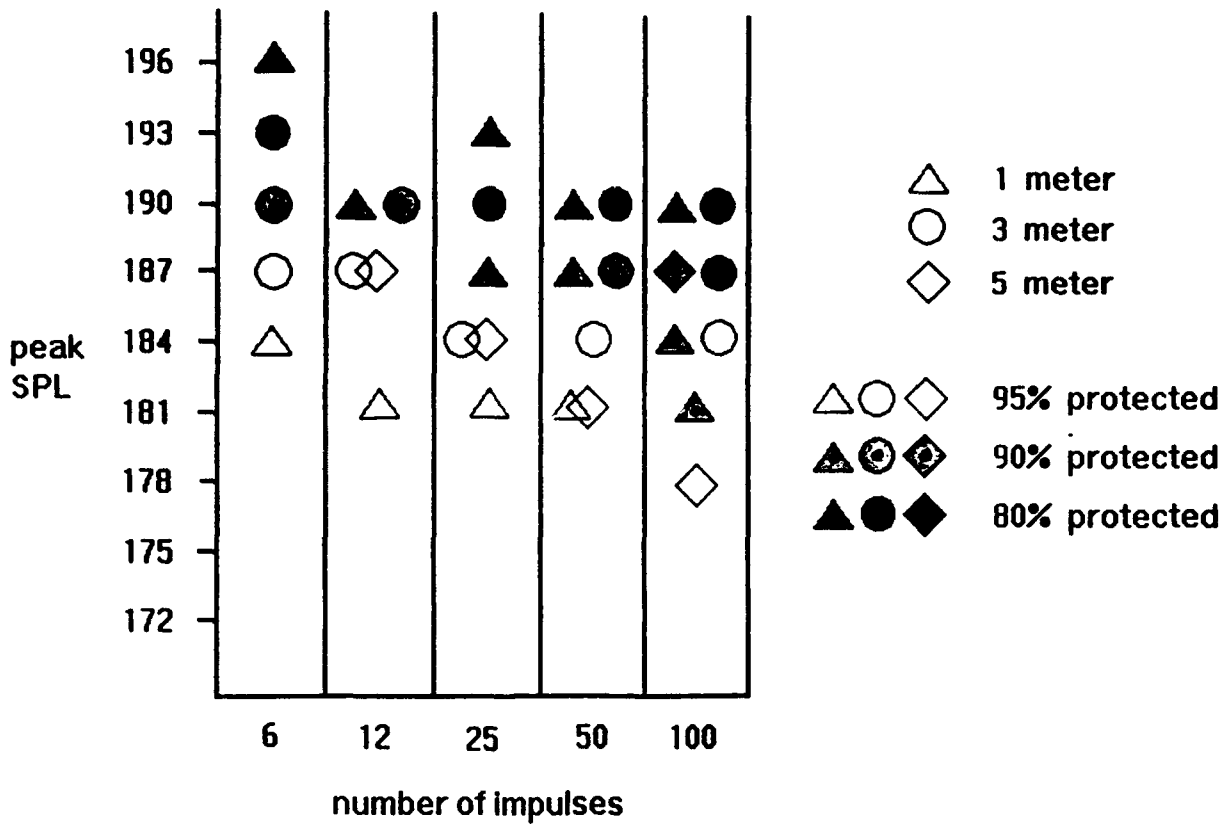


Figure IV-5. Comparison of the Three Distances on an Equal Energy Basis. The modified RACAL® muff is used. The energy of each matrix cell is approximately the same regardless of which study distance was used.

LEVEL, dB	6	12	25	50	100
196					
193					
190	20 10	20			
187		10	20	20	20
184	5		10		
181	5		10		
178			5	5	10
175					5

NUMBER OF EXPOSURES

Figure IV-6. Proposed Safe Peak Levels vs. Number of Exposures for Three Different Percents of the Population Not Protected.

V. CONCLUSIONS

The results from four years of testing of 273 subjects show that with proper hearing protection, the hearing of soldiers can be safeguarded up to impulse exposure conditions that are at the threshold of non-auditory injury. The only caveat to this statement is that, for peak levels above 188 dB, multiple impulses must be separated by 100-msec intervals if muffs are used. This is to prevent exposure to a blast wave while the muff is away from the head from a preceding blast.

In fact, summating all the objective and subjective results, there are fewer problems of all types if the peak SPL's of the blasts are kept below 190 dB. Using the leaking muff, exposures with peak levels in the 187-188-db range were more acceptable from several points of view. First, if TTS did occur it was likely to behave in an expected manner. Second, the subjects clearly expressed more of a willingness to train at these levels than the ones above 190 dB. Third, most of the non-auditory concerns that we found, such as muff movement or arm slapping, disappeared at these levels.

The perforated plug was found to be totally inadequate. Perhaps with additional subjects, the plugs might prove to be safe for shots at 175 dB and below. However, they were not adequate for understanding speech in windy conditions. Thus, there is no valid reason to use them.

In summary, 273 subjects entered the study. No known significant permanent shift in hearing occurred in any subject. As a group, the mean post-hearing levels of the subjects were better at all frequencies than the preexposure means. There were no major injuries to any subjects, the worst injury being a hematoma to the eardrum that took over a week to recover. The exit questionnaires indicate that over 98 percent of the subjects thought the study worthwhile, over 98.5 percent said they were glad they volunteered, and 100 percent of the subjects said they would recommend the study to others. In general, we feel the objectives of the study were met and the study was a success.

(THIS PAGE INTENTIONALLY LEFT BLANK.)

VI. RECOMMENDATIONS

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.

The performance of the perforated plugs was unacceptable and they are not recommended for use under any condition.

(THIS PAGE INTENTIONALLY LEFT BLANK.)

REFERENCES

Alexander, I. E. and Githler, F. J. 1951. Histological examination of cochlear structure following exposure to jet engine noise. J. Comp. Physiol. Psychol. 44: 513-524.

Buck, K., Dancer, A., Lenoir, M., Vassout, P. 1983. Etude de l'influence du niveau de crete etde la durree de bruits impulsionnels, du type bruit de'arme produit en champ libre, sur 1', audition du cobaye. Institut Franco-Allemand de Recherche, Saint-Louis,France: Rapport R 127/83.

CHABA (National Academy of Sciences, National Research Council, Committee on Hearing, Bioacoustics and Biomechanics), 1968. Proposed damage-risk criterion for impulse noise (gunfire), W. D. Ward Ed., Report of Working Group 57.

Chiffelle, T. L. 1966. Pathology of direct air blast injury. Defense Atomic Support Agency, Washington, D.C: DASA 1778.

Coles, R. R., Garinther, G. R., Hodge, D.O. and Rice, O.G. 1968. Hazardous exposure to impulse noise. J. Acoust. Soc. Am. 43: 336-346.

Dancer, A., Parmentier, G., and Vassout, P. 1981. Etude de efets de'une onde de choc forte sur le porc, influence du number de'expositions. Institut Franco-Allemand de Recherche, Saint-Louis, France: Rapport R 904/81.

Daniel, W. 1983. Biostatistics: A foundation for analysis in the health sciences. NY: John Wiley and Sons.

Department of the Army. 1974. Use of volunteers as subjects of research and development. Washington, DC: Department of the Army. AR 70-25.

Department of the Army. 1972. Noise and conservation of hearing. Washington, DC: Department of the Army. TB MED 251.

Department of the Army. 1980. Hearing conservation. Washington, DC: Department of the Army. TB MED 501.

Department of Defense, USA, 1979. Noise limits for Army materiel. MIL-STD-1474B(MI).

Dietz, E. J. and Killeen, T. J. 1981. A nonparametric multivariate test for monotone trend with pharmaceutical applications, J. of the American Statistical Association 76: 169-174.

Faugere, J. J. et al. Auricular blast in warfare. Medecine et Armees, 10(9): 799-805.

Hamernik, R.P. et al. 1983. Anatomical correlates of impulse noise-induced mechanical damage in the cochlea, pp. 229-247, Eisevier Science Publishers, B.V.

Henderson, D., Hamernik, R. P. and Sitler, R. 1974. Audiometric and histological correlates on exposure to 1 msec noise impulses in the Chinchilla. J. Acous. Sc. Am. 56: 1210-1221.

Hirsch, F. G. 1968. Effects of overpressure on the ear--a review. Ann. N.Y. Acad. Sci. 152: 147-162.

Hogg, R. U. and Craig, A. T. 1965. Introduction of mathematical statistics, NY, MacMillan.

Johnson, D. L. and Patterson, J. H. Rating of Hearing Protector Performance for Impulse Noise, Proceedings 1992 Hearing Conservation Conference, University of Kentucky, April 1992. pp 103-106. Also, US Army Aeromedical Research Laboratory, Fort Rucker, AL: USAARL 93-20.

Jonsson, A. 1970. Experimental investigations on the mechanisms of lung injury in blast and impact exposure. Linkoping University Medical Dissertations, Stockholm, No. 880.

Jordan, V. M., Pinheiro, M.L., Chiba, K., and Jimenez, A. 1973. Cochlear pathology in monkeys exposed to impulses noise. Acta Otolaryngol. (Stockholm) Suppl. 312(321): 16-30.

Kryter, K. D. and Garinther, G. R. 1966. Auditory effects of acoustic impulses from firearms. Acta Otolaryngol. Supl. 211.

Mills, J. 1984. Personal communication. University of South Carolina School of Medicine.

Mozo, B. T., Patterson, J. H., Marrow, R., Nelson, W. R., Lomba-Gautier, M. and Curd, D. L. 1984. Development of a microprocessor based audiometer for threshold shift studies. Ft Rucker, AL: U. S. Army Aeromedical Research Laboratory, USAARL Report No 84-7.

NATO (Defence Research Group, Panel on the Defence Applications of Human and Bio-Medical Sciences, Research Study Group on the Effects of impulse Noise), 1987. Effects of impulse noise. Document AC/243 (Panel 8/RAG.6) D/9.

Patterson, J. H., Mozo, B. T. and Camp, R. T. 1977. Frequency dependence of impulse noise attenuation. Ft Rucker,Al: US Army Aeromedical Research laboratory, USAARL Report No. 77-15.

Patterson, J. H., Looa-Gatier, I. M., Curd, D. L., Hamernik, R. P., Salvi, R.J., Hargett, C. E., and Turrentine, G. 1985. The

effect of impulse noise on hearing and cochlear pathology in the chinchilla. Ft Rucker, AL: US Army Aeromedical Research Laboratory, USAARL Report No. 85-3.

Patterson, J. H., and Johnson, D. L. Effects of high-intensity impulse noise on the hearing of humans wearing hearing protection. J. Acous. Soc. Am., 93: 4(2). (Abstract)

Patterson, J.H., Mozo, B. T., Marrow, R. H., McConnell, R.W., Lamba-Gaulter, I., Curd, D. L., Phillips, Y. Y. and Henderson, R. 1985. Direct determination of the adequacy of hearing protective devices for use with the M198, 155-mm towed howitzer. Ft Rucker, AL: US Army Aeromedical Research Laboratory, USAARL Report No. 85-14.

Patterson, J. H., and Johnson, D. L. 1990. Determination of occupational noise exposure limits for very high-intensity impulses when hearing protection is used. J. Acous. Soc. Am. Suppl. 88(1).

Patterson, J. H., Jr., Mozo, B. T., and Johnson, D. L. 1993. Actual effectiveness of hearing protection in high level impulse noise. Proceedings 6th International Congress on Noise as a Public Health Problem, Nice, France.

Pfander, F., Bongartz, H. and Brinkmann, H. 1975. Das Kanll-trauma, Springer-Verlag.

Pfander, F., Bongartz, H., Brinkmann, H. and Case, H. 1980. Danger of auditory impairment from impulse noise: a comparative study of the CABBY damage-risk criteria and those of the Federal Republic of German, J. Acous. Soc. Am. 67: 628-633.

Pander, F. 1984. Grenzen swischen normaler und pathologischer Hoermudung nach akusticher Belastung mit hohen Spitzendrucken in ihrer Bedeutung fur die Voraussage akustisch bedingter Horschaden. Laryng. Rhinol. Otol. 63.

Phillips, Y. Y., Jaeger, J. J. and Young, A. J. 1982. Biophysics of injury from repeated blast. Proceedings of Tripartite Technology Coordinating Program Panel WE-2 Muzzle Blast Overpressure Workshop.

Price, G. R. 1982. Rating the hazard from intense sounds: putting theory into practice. In Hearing and Hearing Prophylaxis. Borghgrevink, H. M. Ed. Scandinavian Audiology Supplementum 16.

Price, G. R. 1983. Relative hazards of weapons impulses. J. Acous. Soc. Am. 73: 556-566.

Richmond, D. R., Yelverton, J. T. and Fletcher, E. R. 1981. The

biological effects of repeated blasts. Defense Nuclear Agency, Washington, DC: Report DNA-5842F.

Richmond, D. R., Damon, E. G., Fletcher, E.R., Bowen,I. G. and White, C. S. 1968. The relationship between selected blast wave parameters and the response of mammals exposed to air blast. Ann. of NY Acad. of Sci. 152: 103-121.

Smoorenburg, G. F. 1982. Damage risk criteria for impulse noise. In Perspectives on Noise-Induced Hearing Loss. Hamernik, R., P., Henderson, D., and Salvi, R. Eds. NY: Raven Press.

Smoorenburg, G. F. 1984. Letter Summary of Summary of NATO Panel VIII RAG-6 Fifth Meeting.

Spoendlin, H. H. 1976. Anatomical changes following various noise exposures. In The Effects of Noise on Hearing. Henderson, D., Dosanjh, D. S., Hamernik, R. P. and Mills, J. Eds. NY: Raven Press.

Tonndorf, J. 1976. Relationship between the transmission characteristics of the conductive system and noise-induced hearing loss. In The Effects of Noise on Hearing. Henderson, D., Dosanhj, D. S., Hamernik, R.P. and Mills, J. Eds. NY: Raven Press.

Vassout, P., Dancer, A., Richmond, D., and Phillips, Y. Effets biologiques des ondes de choc fortes: influence de la durree des ondes dans de cas d'expositions repetees. Institut Franco-Allemand de Recherces, Saint-Louis, France: Notice S-N 911/84.

Ward, W. D., Selters, W. and Glorig, A. 1961. Exploratory studies on temporary threshold shift from impulses. J. Acous. Soc. Am. 33: 781-793.

White, C. S. 1968. Part II. Personnel sensitivity, the scope of blast and shock biology and problem areas in relating physical and biological parameters. Ann. N.Y. Acad. of Sci. 152: 89-102.

White, C. S., Jones, R. K., Damon, E. G. and Fletcher, E. R. 1971. The biodynamics of airblast. Defense Nuclear Agency, Washington, DC: Report DNA-2738T.

Yelverton, J. T., Richmond, D. R. and Fletcher, E. R. 1983. Bioeffects of simulated muzzle blasts. Proceedings of the Eighth International Symposium on Military Application on Blast Simulation, Spiez, Switzerland.

LIST OF PUBLICATIONS AND PRESENTATIONS

Johnson, D. L. and Patterson, J. H. Rating of Hearing Protector Performance for Impulse Noise, Proceedings 1992 Hearing Conservation Conference, University of Kentucky, April 1992. pp 103-106. Also, US Army Aeromedical Research Laboratory, Fort Rucker, AL: USAARL 93-20.

Patterson, J. H., and Johnson, D. L. 1993. Effects of high-intensity impulse noise on the hearing of humans wearing hearing protection. J. Acous. Soc. Am. 93: 4(2) (Abstract)

Patterson, J. H., and Johnson, D. L. 1990. Determination of occupational noise exposure limits for very high-intensity impulses when hearing protection is used. J. Acous. Soc. Am. Suppl. 88(1).

Patterson, J. H., Jr., Mozo, B. T., and Johnson, D. L. 1993. Actual effectiveness of hearing protection in high level impulse noise. Proceedings 6th International Congress on Noise as a Public Health Problem, Nice, France.

APPENDIX A. TYPICAL VOLUNTEER CONSENT FORM AND REGISTRY DATA SHEET

VOLUNTEER AGREEMENT AFFIDAVIT

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

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087.

Principle 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(1) - 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/give consent as legal representative for _____ to participate in _____

DIRECT DETERMINATION OF OCCUPATIONAL EXPOSURE LIMITS FOR FREEFIELD IMPULSE NOISE

(Research Study)

under the direction of Dr. Daniel L. Johnson Commercial: 505-846-4252 or -4253 Autovon: 246-4252

conducted at EG&G Special Projects, Kirtland Air Force Base, New Mexico.

(Name of Institution)

The implications of my voluntary participation/consent as legal representative; 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/the rights of the person I represent on study-related injury, I may contact

Staff Judge Advocate, SGRD-AJ, U.S. Army Medical Research and Development Command

at Fort Detrick, MD 21701-5012; DSN: 343-2065; 301-663-2065

(Name, Address and Phone Number of Hospital (Include Area Code))

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

_____

PART A (2) - ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD)*

I, _____, SSN _____ having full capacity to consent and having attained my _____ birthday, do hereby volunteer for _____

_____ to participate in _____

_____

(Research Study)

_____

under the direction of _____

conducted at _____

(Name of Institution)

PART A(2) - ASSENT VOLUNTEER AFFIDAVIT (*MINOR CHILD*) *(Cont'd.)*

The implications of my voluntary participation; the nature, 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 I may contact

_____

at _____

(Name, Address, and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examination 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.

_____

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT. *(Provide a detailed explanation in accordance with Appendix E, 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	SIGNATURE OF LEGAL GUARDIAN *(If volunteer is a minor)*
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 mortars, howitzers, and other large weapons fired in the open 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 and Development Command (USAMRDC). 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 living in the KAFB BEQ. 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 a platform placed on an open concrete pad and the source of BOP will be an explosive charge detonated within a steel tube to simulate noise made by a mortar. No actual weapons will be used. You will be instructed to sit at a given distance (28-29 inches) from the opening of a blast tube. You will begin your exposures wearing ear muffs and the first test condition will be six exposures 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 test 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 ear plugs, 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 any change of 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 throat 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 Army Surgeon General (MIL-STD-1474B). Some following conditions will exceed what is now allowed in training.

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 large animals. Work with hundreds of animals (sheep and pigs) has shown that injury to the throat occurs long before injury occurs in the lungs or intestines. We have carefully determined what strength of blast wave, when given 6, 25 or 100 times, causes a barely detectable bruising in the throats 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 throat will be examined before any blast exposures after 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. 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.

The results of this study will be used in deciding how to protect the hearing of the Army crews who will serve artillery and mortar systems. **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 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 this 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: Staff Judge Advocate, SGRD-AJ, U.S. Army Medical Research and Development Command, Fort Detrick, Frederick, MD. 21702-5012; DSN: 343-2065 or (303) 663-2065.

HANDLING OF DATA

All research data will be treated as confidential. No information linked to you by name or other identifiers will be released without your express written permission. Only if a serious medical incident occurs will any information beyond an indication of your participation be placed in your health records. 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.

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 Clyde D. Byrne
U.S. Army Aeromedical Research Laboratory
(205) 255-6923

CPT Jennifer Johnson
Blast Overpressure Site
(505) 846-8497

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

Signature of 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

Title Date

TEST 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 this session.

1. When can you withdraw from this study?

   a) first week
   b) second week
   c) anytime
   d) 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 windpipe
   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

5. Is there any possibility that you may be slightly injured during one of the required physical examinations?

   a) Yes
   b) No

_____ _____
Signature Date

_____
SSAN

Revised 30 September 1991

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-4864 2. Protocol Title: Direct Determination of Occupational Exposure Limit for Freefield Impulse Noise

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

4. Study Period: From: 01/ 05/ 89 (DA/MO/YR) To: 01/ 05/ 94 (DA/MO/YR)

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

(1) JOHNSON, DANIEL I. (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. ( ) -

Revised 30 September 1991

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

PART C-ADDITIONAL INFORMATION

(To Be Completed By Investigator)

...SE PRINT, USING INK OR BALLPOINT PEN

16. Location of Study: Blast Overpressure Test Site, Kirtland AFB, Albuquerque, NM

17. Is Study Completed: Y___ N_x

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.

DATE

Sensory Research Division

NAME
ADDRESS

Dear ,

During your participation in the Blast Overpressure (BOP) research study in Albuquerque, NM, entitled "Direct Determination of Occupational Exposure Limits for Freefield Impulse Noise," photographs, motion pictures, and/or video recordings were collected as part of the research documentation of the project. We would like your permission to use these materials in public presentations and published 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. Your consent to the use of these materials is voluntary and no penalty or loss of benefits will result if you refuse.

Enclosed you will find a permission statement. If you consent, please sign this statement, seal it in the preaddressed envelop, and take it to your mail room as soon as possible. Your cooperation is appreciated.

SIGNATURE BLOCK

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

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

_____

Signature & 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:

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

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

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

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 expsoures 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 e[illegible]sure 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 (TTS) 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 TTS of 20 dB, we might expect a TTS 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 of TTS were adopted for developing the failure criteria. The archetypical TTS pattern was a true TTS of zero at all except one frequency. Within the Monte Carlo simulation it does not matter which frequency shows the non-zero TTS. A second pattern, had two non-zero frequencies. The third consisted of a pattern in which 4.0 kHz shows the largest TTS and 0.5 kHz and below show no TTS while frequencies between 0.5 and 4 kHz and frequencies between 4 and 8 kHz show a TTS that gets progressively smaller as the frequency moves away from 4 kHZ. This pattern is similar to TTS observed in human experiments (Ward et al, 1961).

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

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

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 TTS 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 TTS 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 TTS target level for the conditional failure is set to 15 dB.

These criteria for the three archetypical TTS 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 TTS patterns other than the ones for which they were developed, another Monte Carlo

simulation was undertaken. This time random patterns of TTS were generated subject to the constraint that the maximum TTS in a pattern was uniformly distributed over the interval from 0 to 40 dB. All other TTS were uniformly distributed over the interval from 0 to maximum TTS. Using these patterns, estimates of the probabilities of the two types of errors (false pass and false failure) were estimated when the maximum TTS was 15, 20, and 25 dB. These probabilities are summarized in Table D-1. 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 TTS 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 TTS 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 TTS 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 6-8 of the 240 subjects planned for the study might pass an exposure when their TTS is marginal (20 dB). They could then be exposed to a double-energy condition which might produce a TTS 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.

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

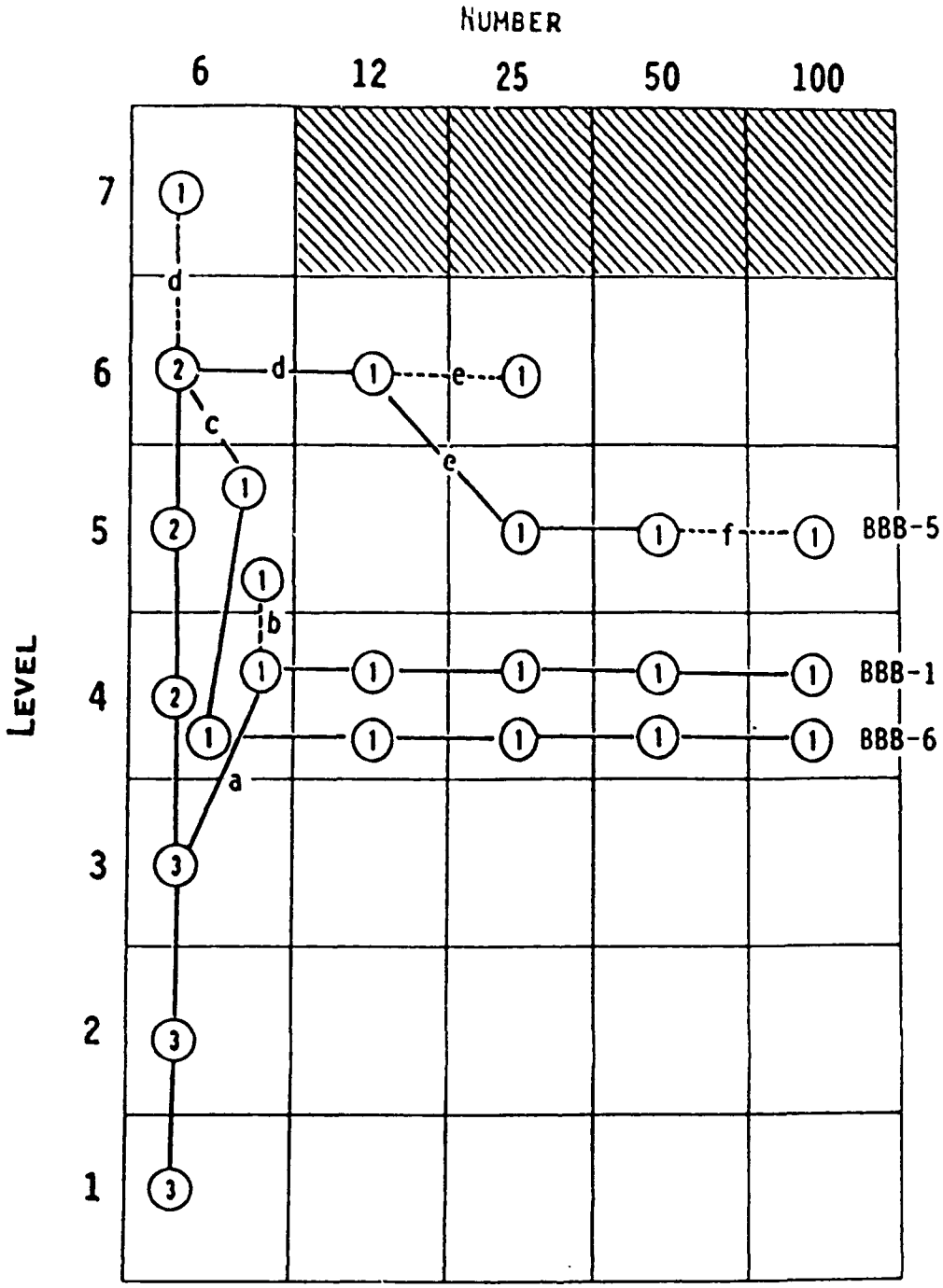


Figure E-1. GROUP BBB, SEPTEMBER-OCTOBER 1989. 5-M Distance, Unmodified Muff.

a. BBB-1 delayed on 21 September one day because of upset stomach.
b. BBB-1 elected not to go to Level 5.
c. BBB6 had nonauditory failure after Level 6 and then after Level 5.
d. BBB-5 not allowed to go to Level 7 (PI discretion).
e. BBB-5 elected to continue at Level 5.
f. BBB-5 terminated after 50 exposures at Level 5 for disciplinary reasons.

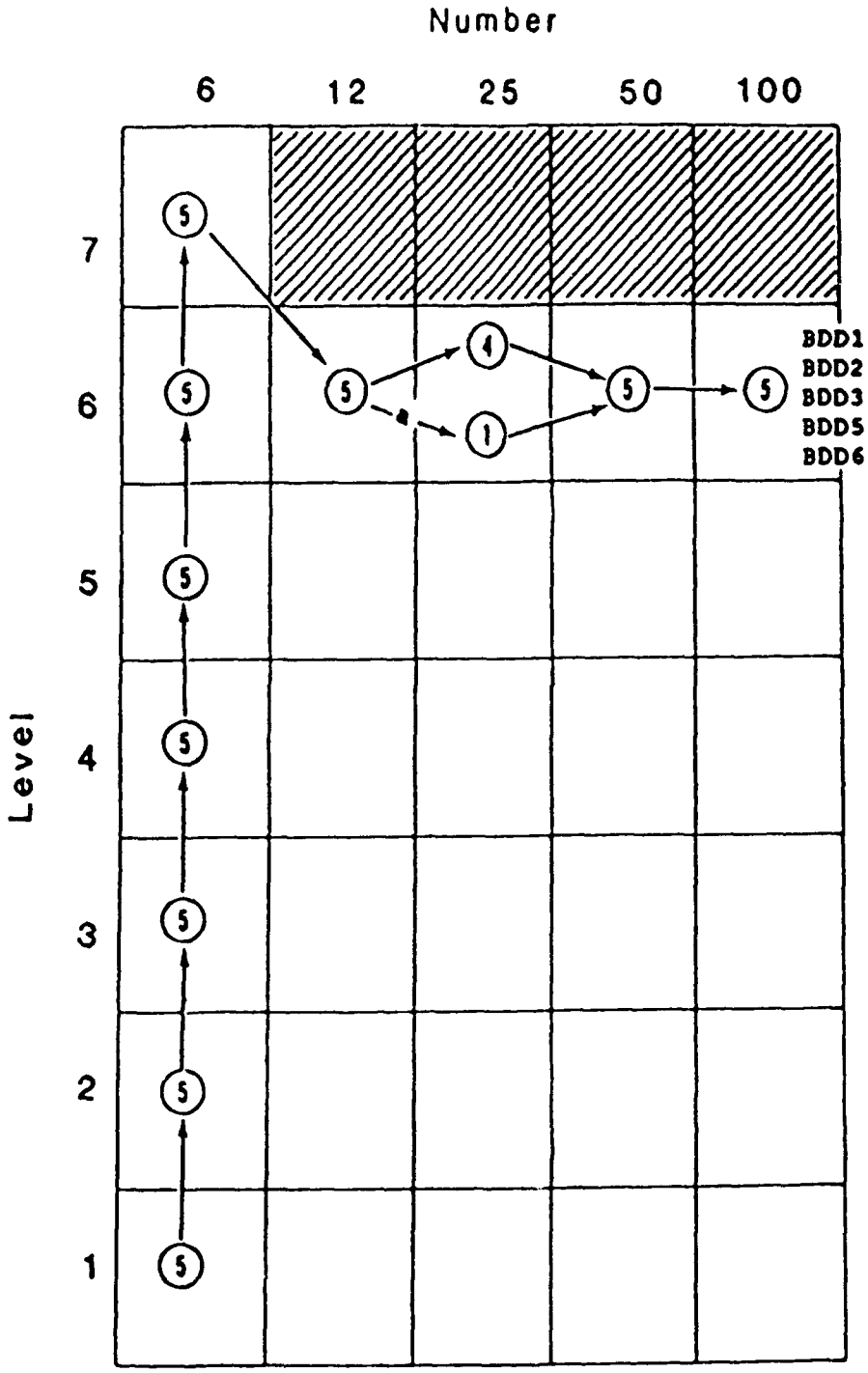


Figure E-2. GROUP BDD, JANUARY-FEBRUARY 1990. 5-M Distance, Unmodified Muff.

a. BBD-5 delayed one day because of stomach cramps. Caught up at Level 6/25.

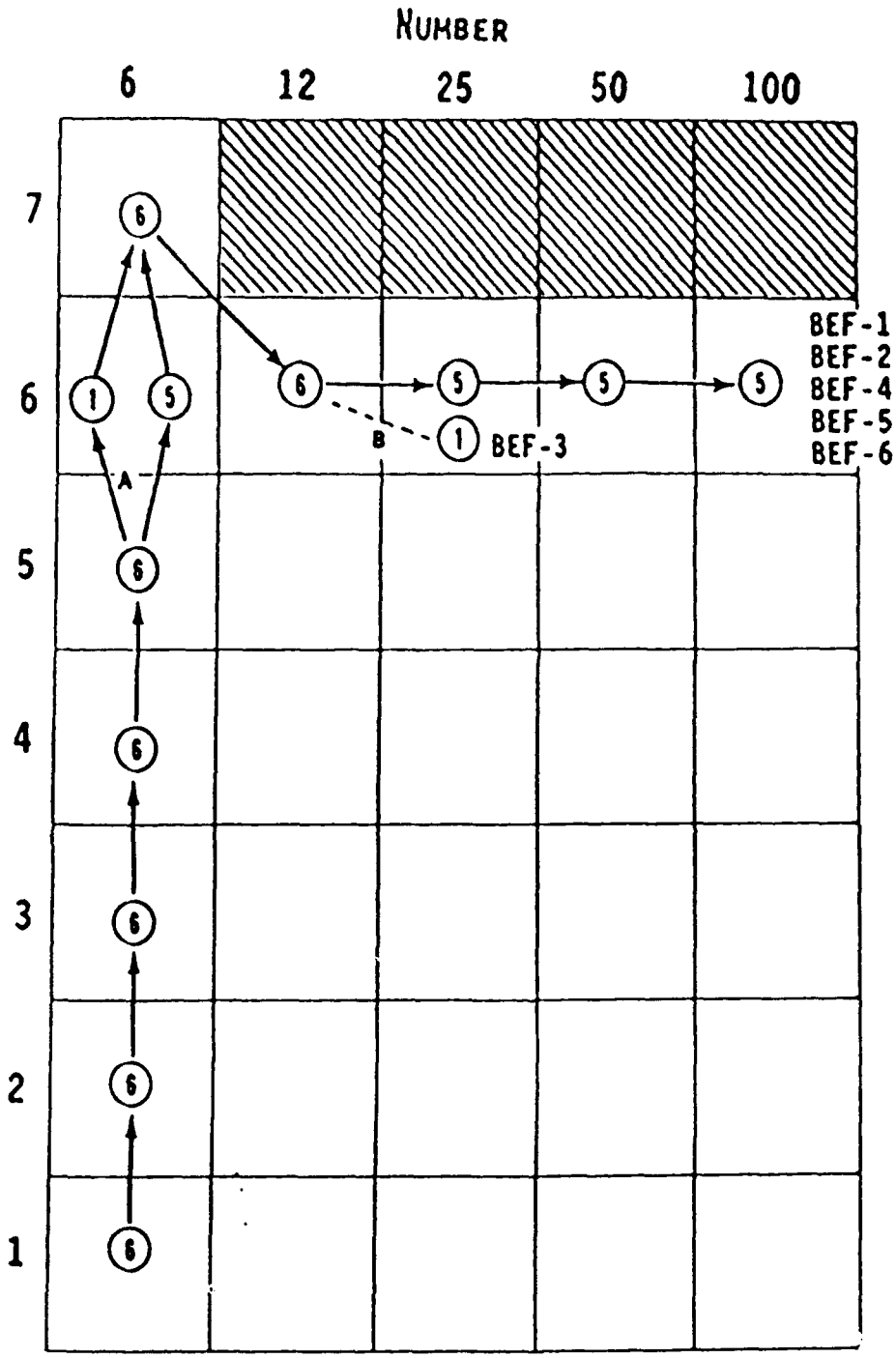


Figure E-3. GROUP BEF, MARCH-APRIL 1990. 5-M Distance, Unmodified Muff.

a. BEF-3 delayed one day because of headache.
b. BEF-3 elected to stop after Level 6/12.

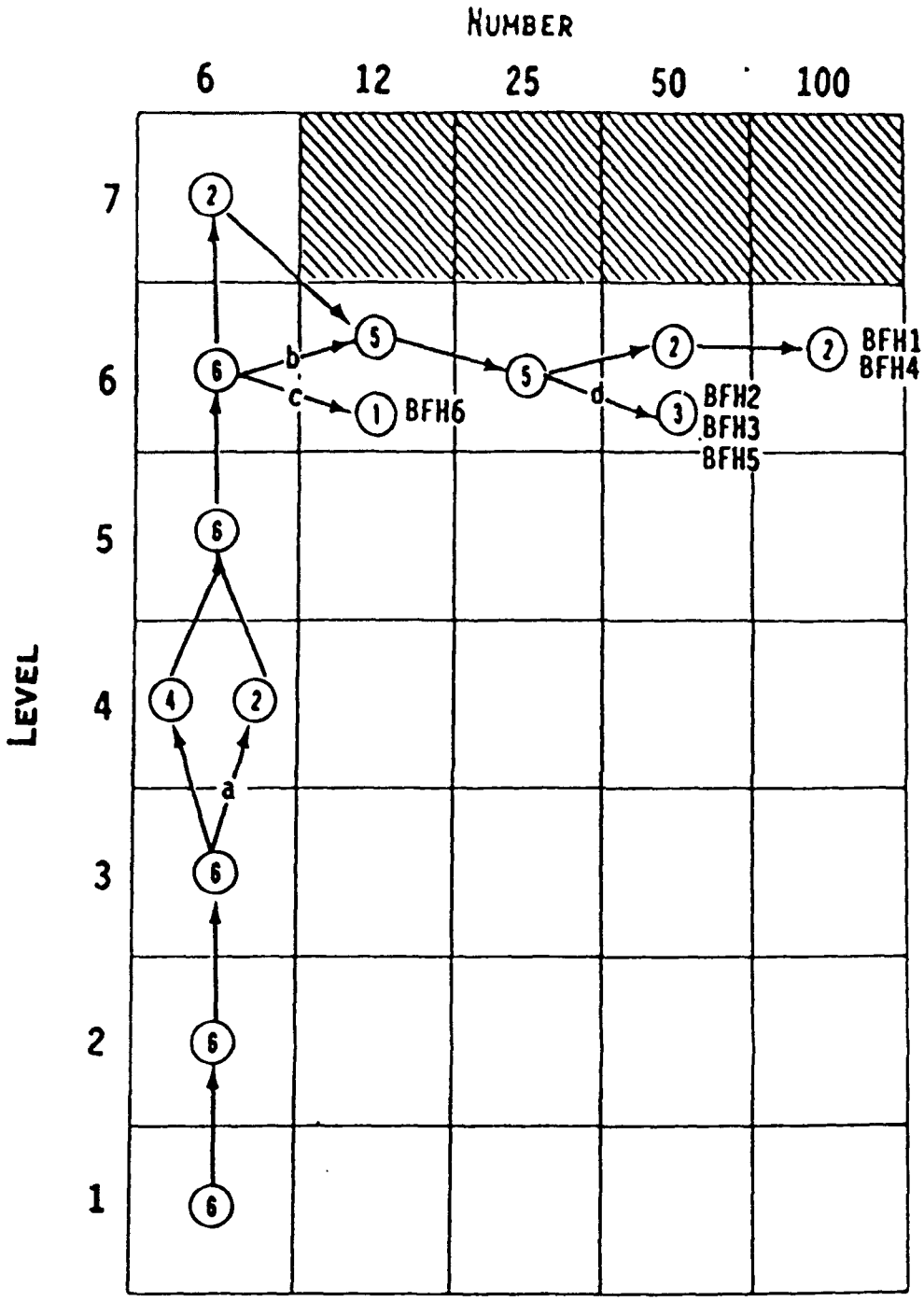


Figure E-4. GROUP BFH, APRIL-MAY 1990. 5-M Distance, Unmodified Muff.

a. BFH2 and BFH5 delayed due to flu.
b. BFH2, BFH3, and BFH5 elected not to go to Level 7.
c. BFH6 elected not to go to either Level 7 or to Level 6/12.
d. BFH2, BFH3, and BFH5 elected to quit after Level 6/25.

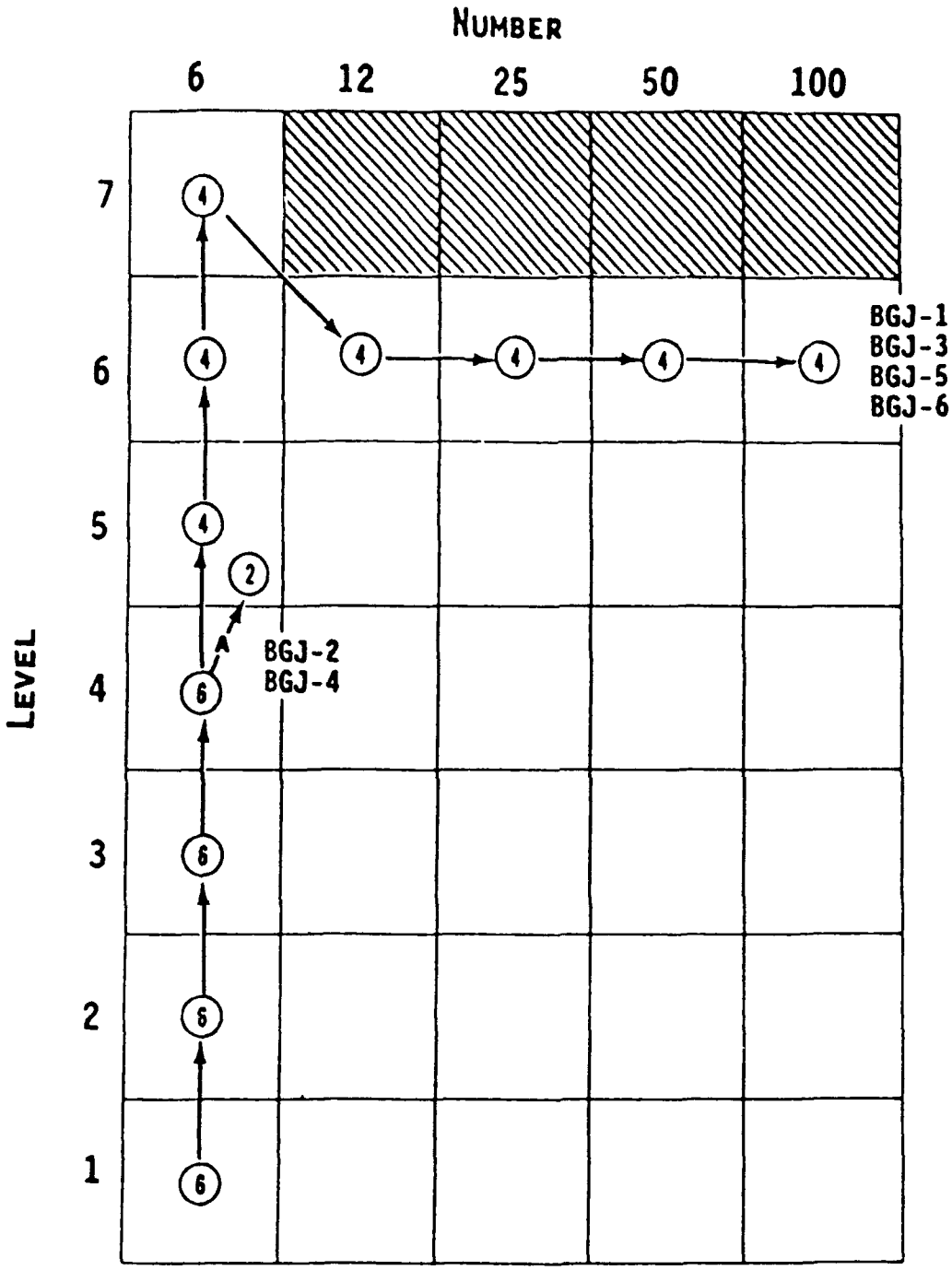


Figure E-5. GROUP BGJ, JUNE-JULY 1990. 5-M Distance, Unmodified Muff.

a. BGJ-1 and BGJ-4 administratively dropped from study after Level 4.

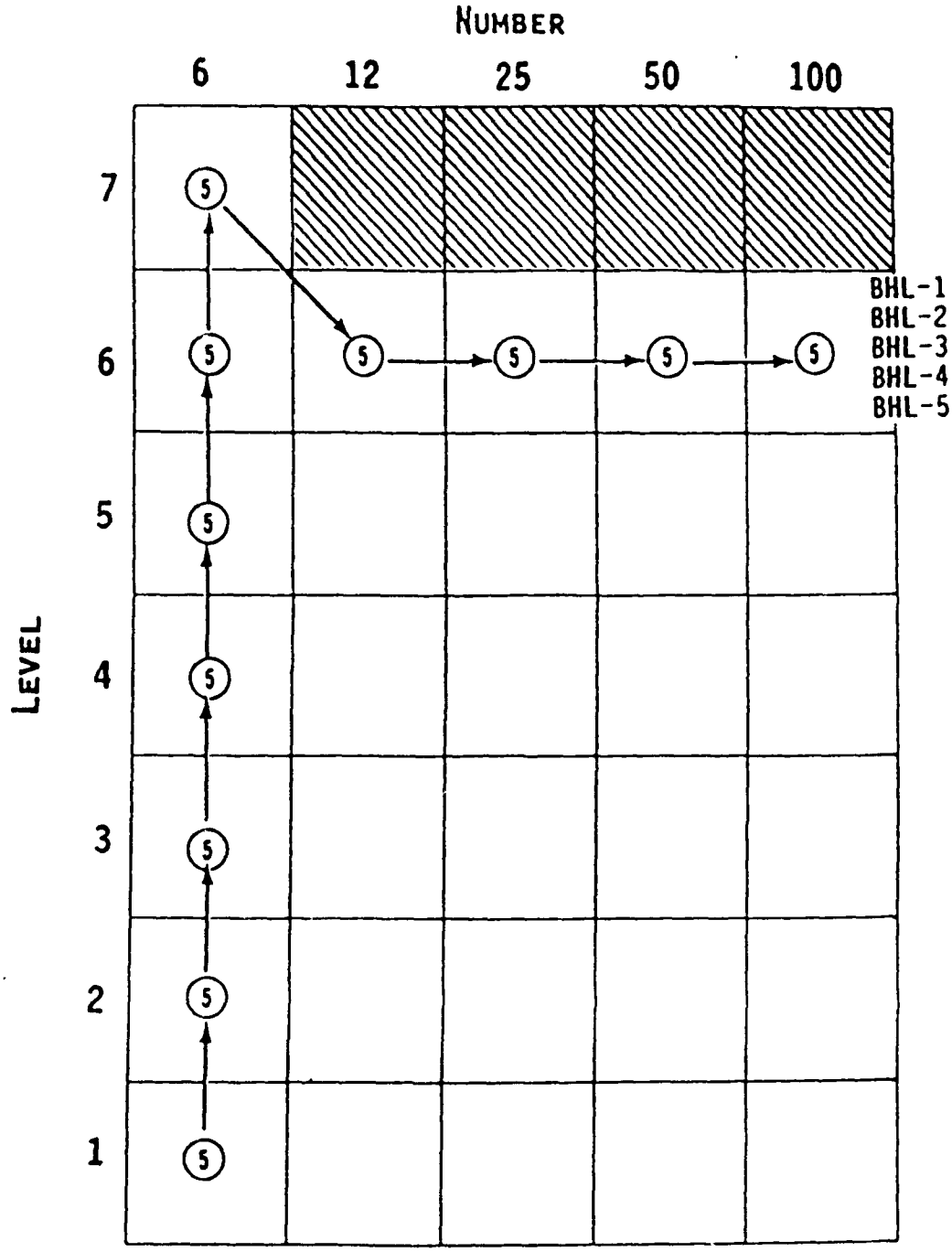


Figure E-6. GROUP BHL, AUGUST 1990. 5-M Distance, Unmodified Muff.

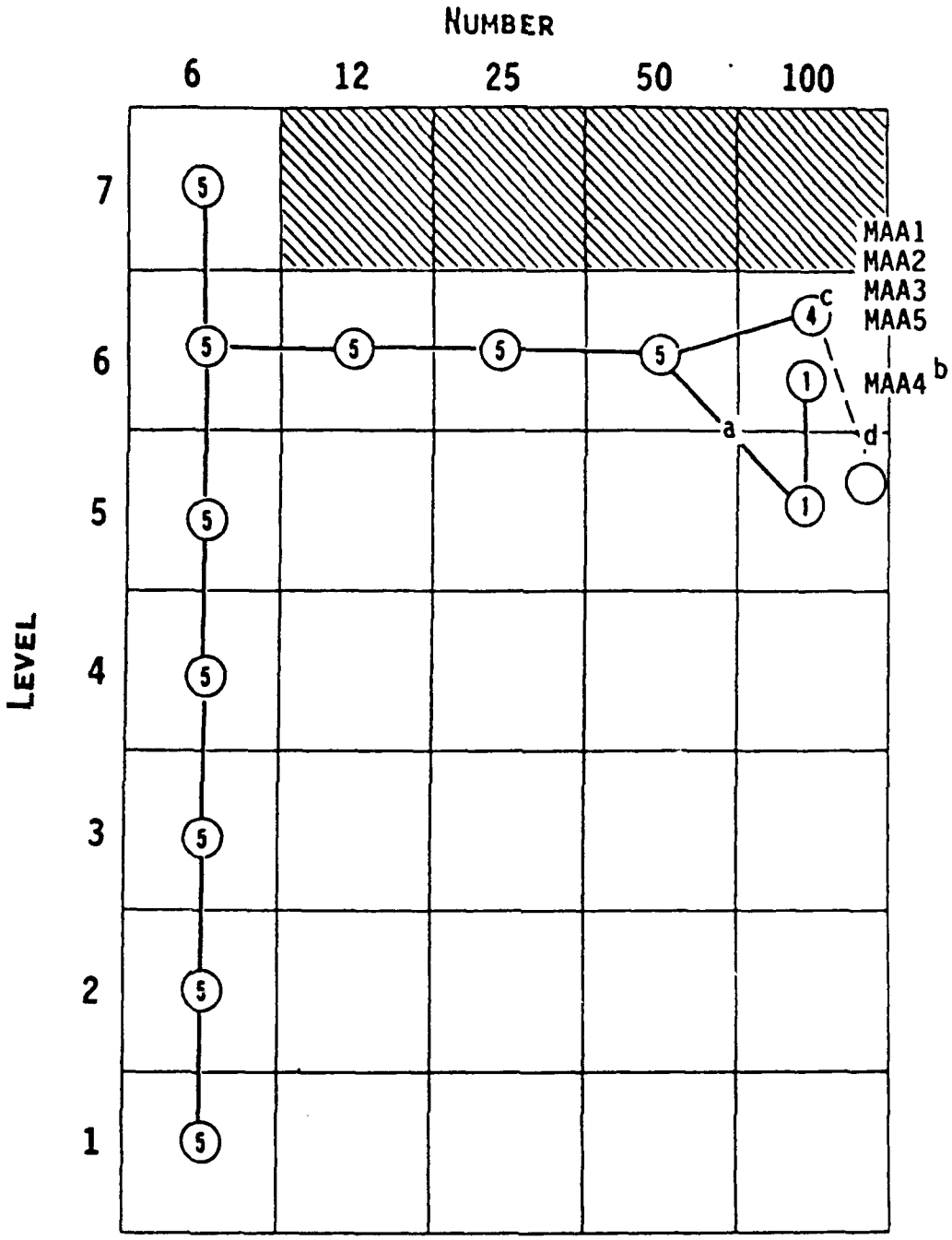


Figure E-7. GROUP MAA, SEPTEMBER-OCTOBER 1990. 5-M Distance, Modified Muff.

a. MAA4 had conditional auditory failure at 6/50.
b. MAA4 was only exposed to 55 shots.
c. After 6/100 MAA2 had auditory failure and MAA5 had conditional auditory failure of 18 dB at 4 kHz. This grew to 27 dB at 20 min, then recovered.
d. MAA2 was ot exposed to 5/100. This was PI decision.

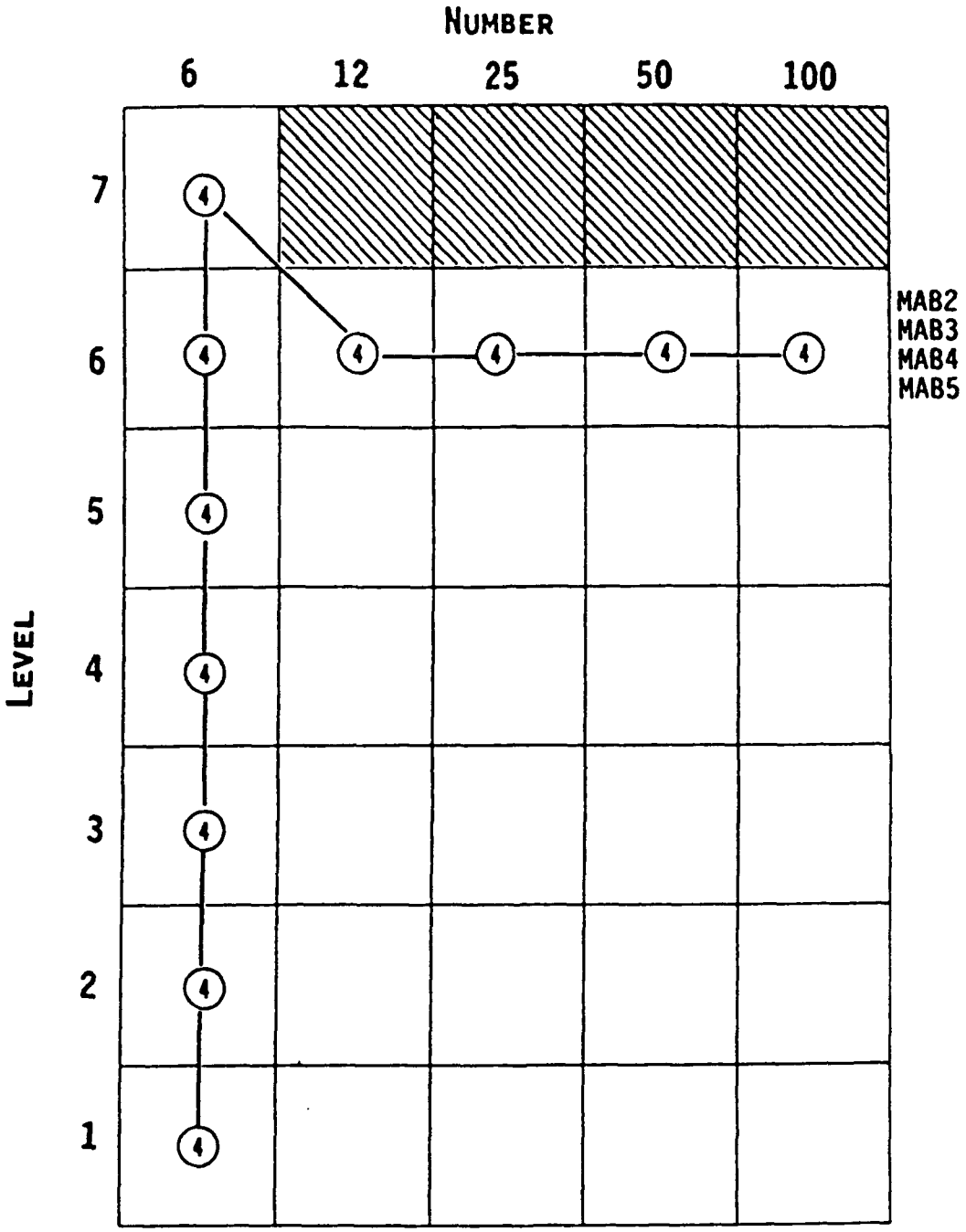


Figure E-8. GROUP MAB, SEPTEMBER-OCTOBER 1990. 5-M Distance, Modified Muff.

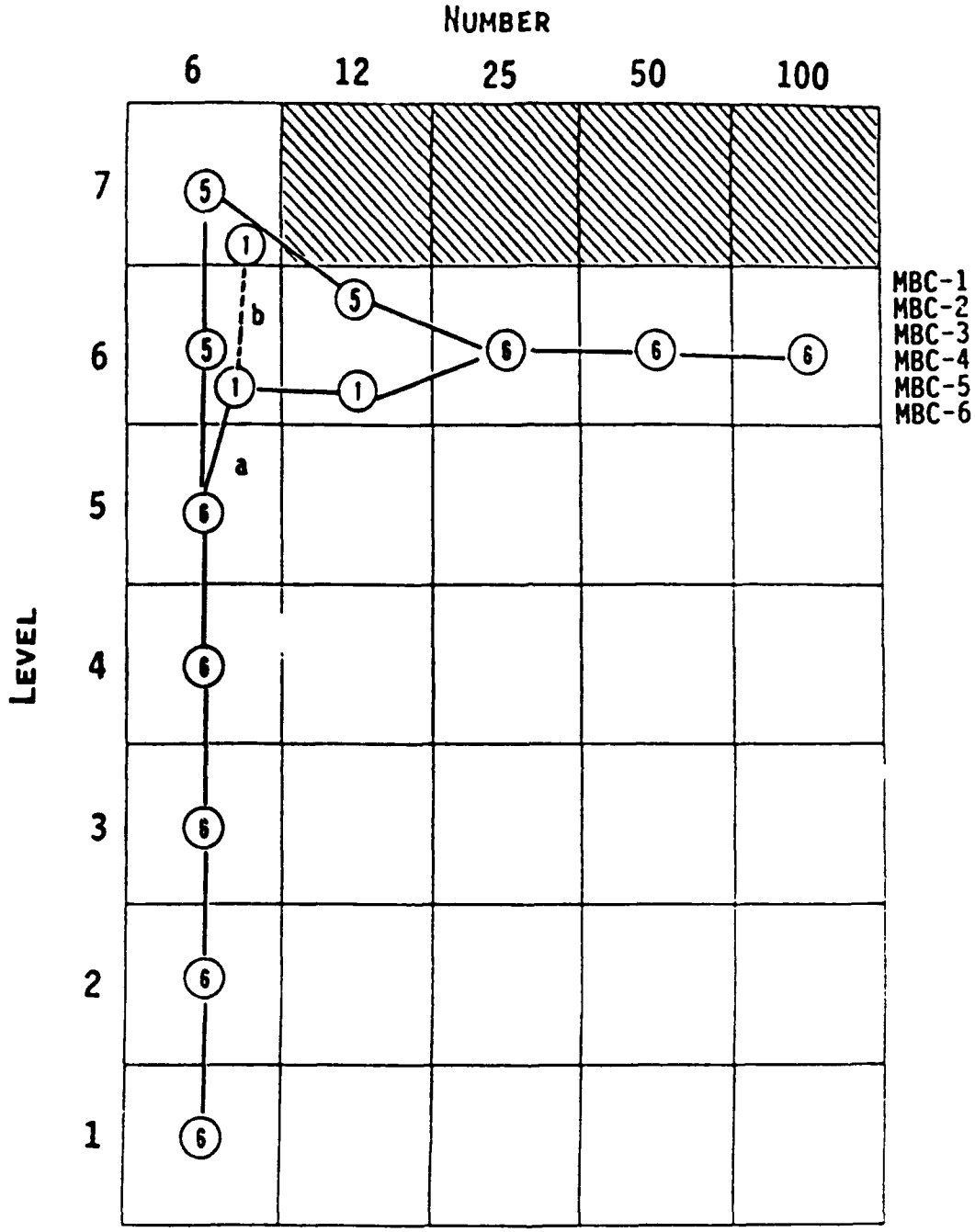


Figure E-9. GROUP MBC, NOVEMBER 1990. 5-M Distance, Modified Muff.

a. Subject MBC-3 had inflammed tonsils and elevated thresholds. Not exposed for 2 days. Caught up with group for 6/25.

b. Subject MBC-3agreed to be exposed to 7/6 after 6/100 in order to catch up with group. After the 6/100 exposure, he elected not to be exposed to 7/6. Thus, he is an elective failure for 7/6.

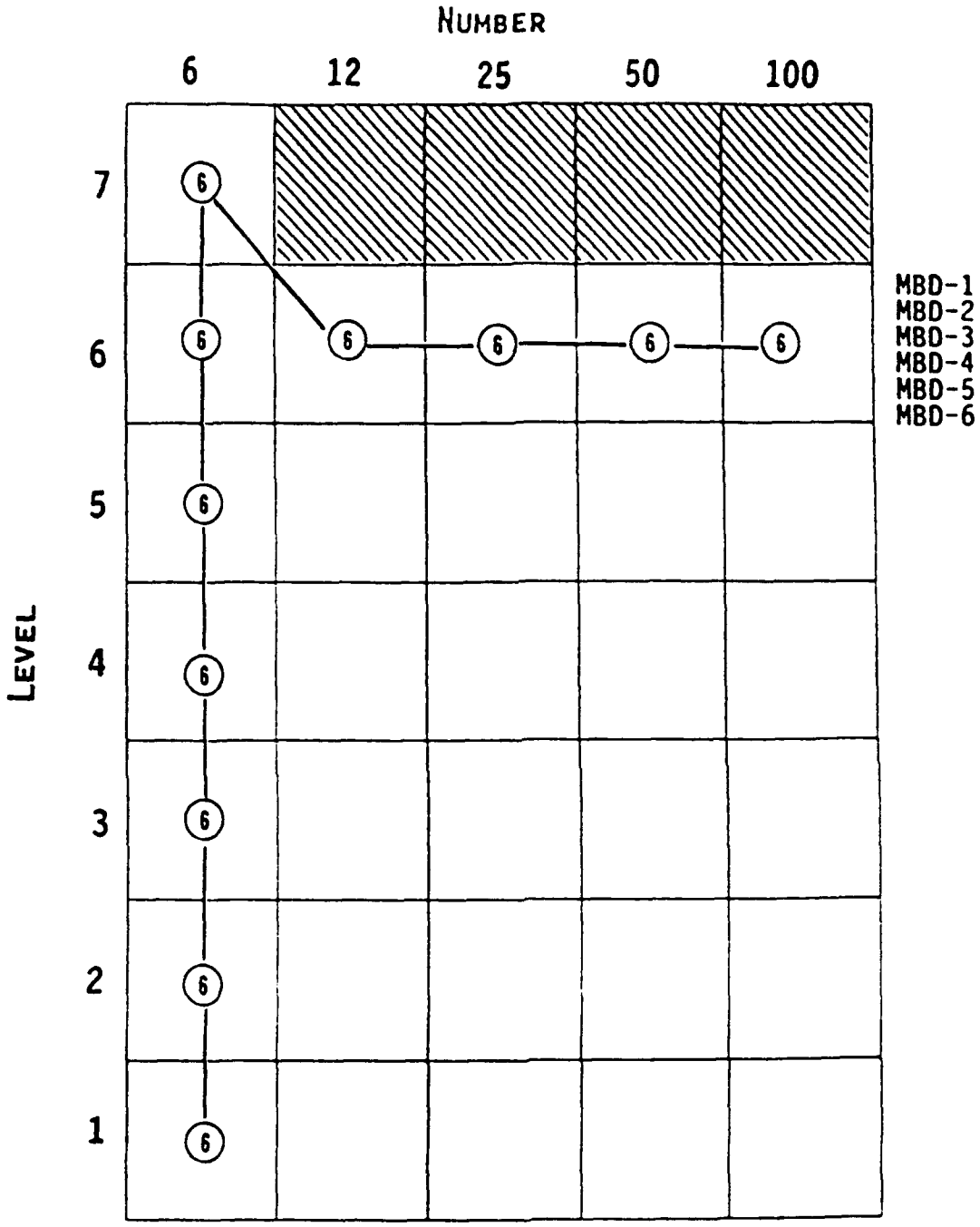


Figure E-10. GROUP MBD, NOVEMBER 1990. 5-M Distance, Modified Muff.

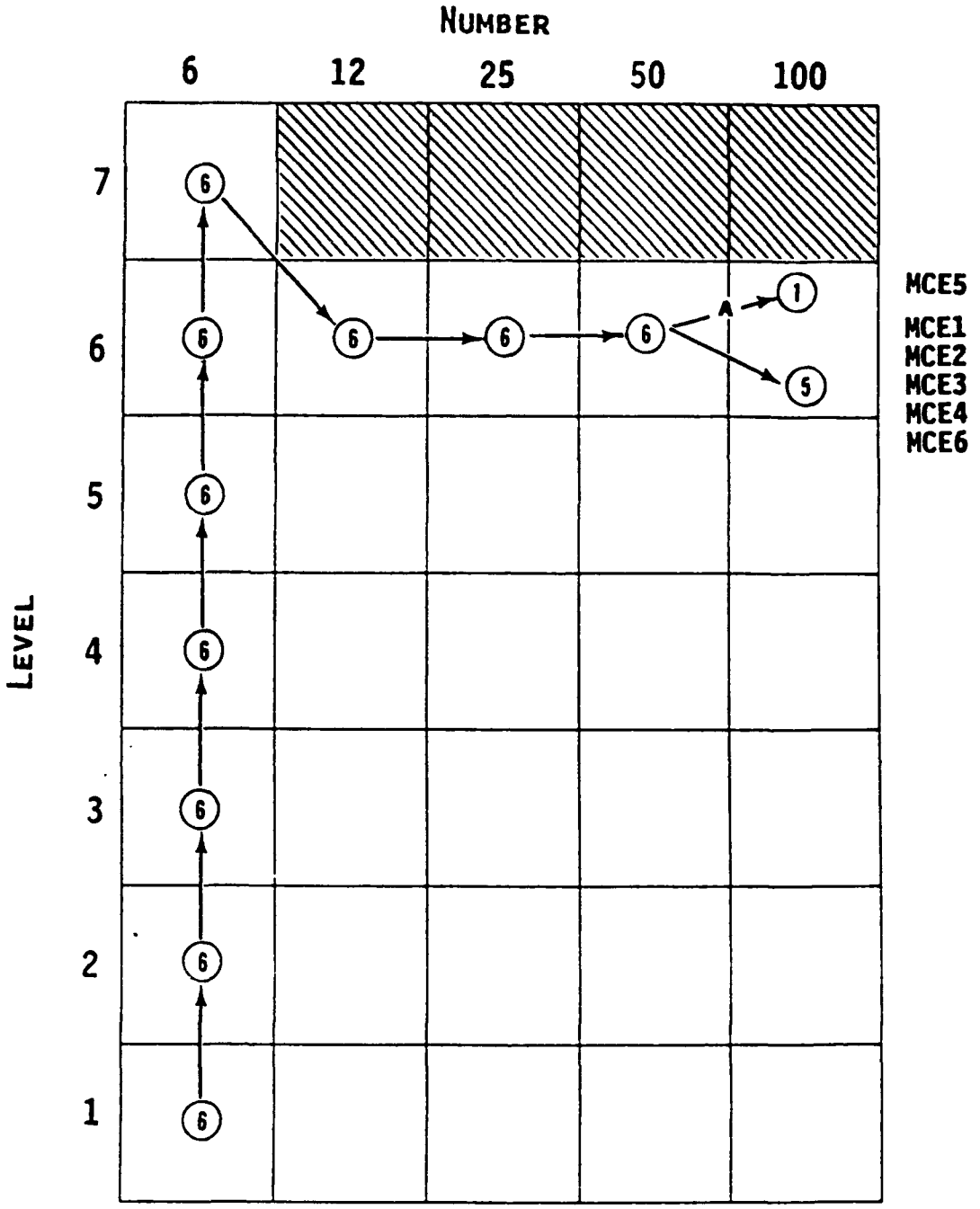


Figure E-11. GROUP MCE, JANUARY 1991. 5-M Distance, Modified Muff.

a. Subject MCE5 was exposed to 6/100 on January 30 with Group MCF, replacing MCF5.

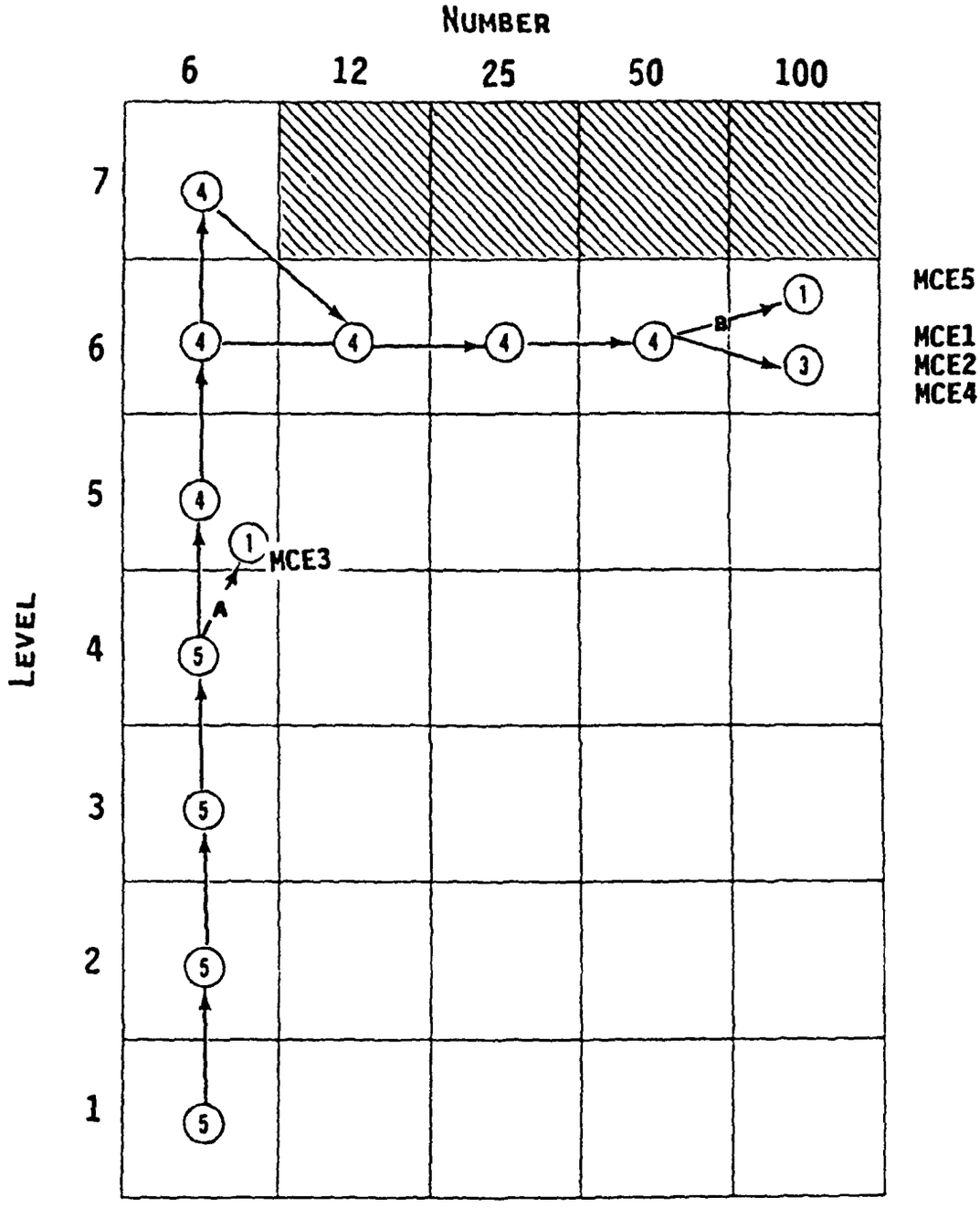


Figure E-12. GROUP MCF, JANUARY 1991. 5-M Distance, Modified Muff.

a. MCF3 was eliminated from going beyond level 4/6 because of excessive TTS at 3 kHz from attending a rock concert on January 19, 1991.

b. MCF5 was sick on January 30, 1991 so we received his level 6/100 exposure on January 31 with Group MCE.

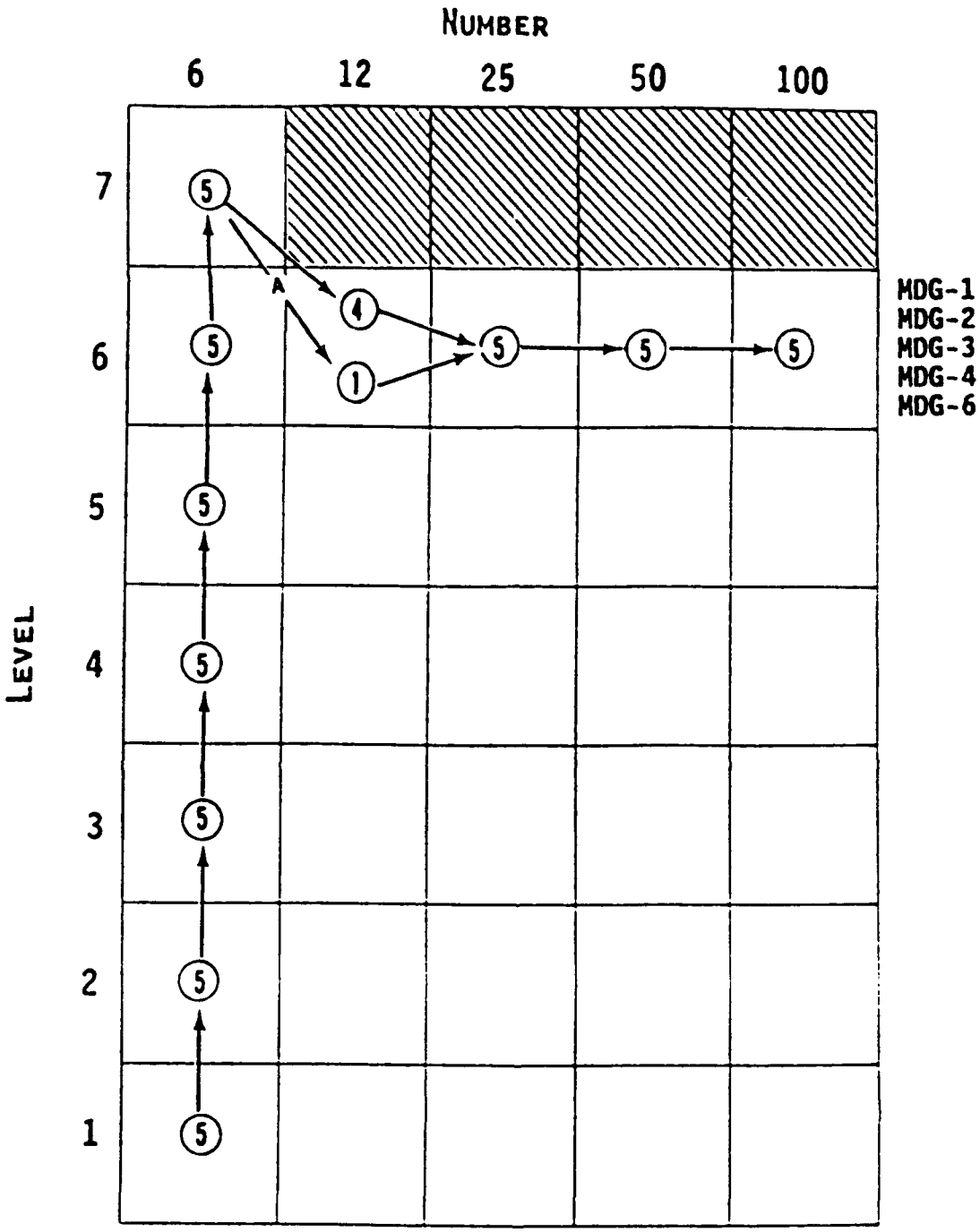


Figure E-13. GROUP MDG, FEBRUARY-MARCH 1991. 5-M Distance, Modified Muff.

a. MDG-6 delayed for severe cold and was exposed by himself on 11 March 1991.
b. First exposure on 26 February 1991 and last exposure on 15 March 1991.

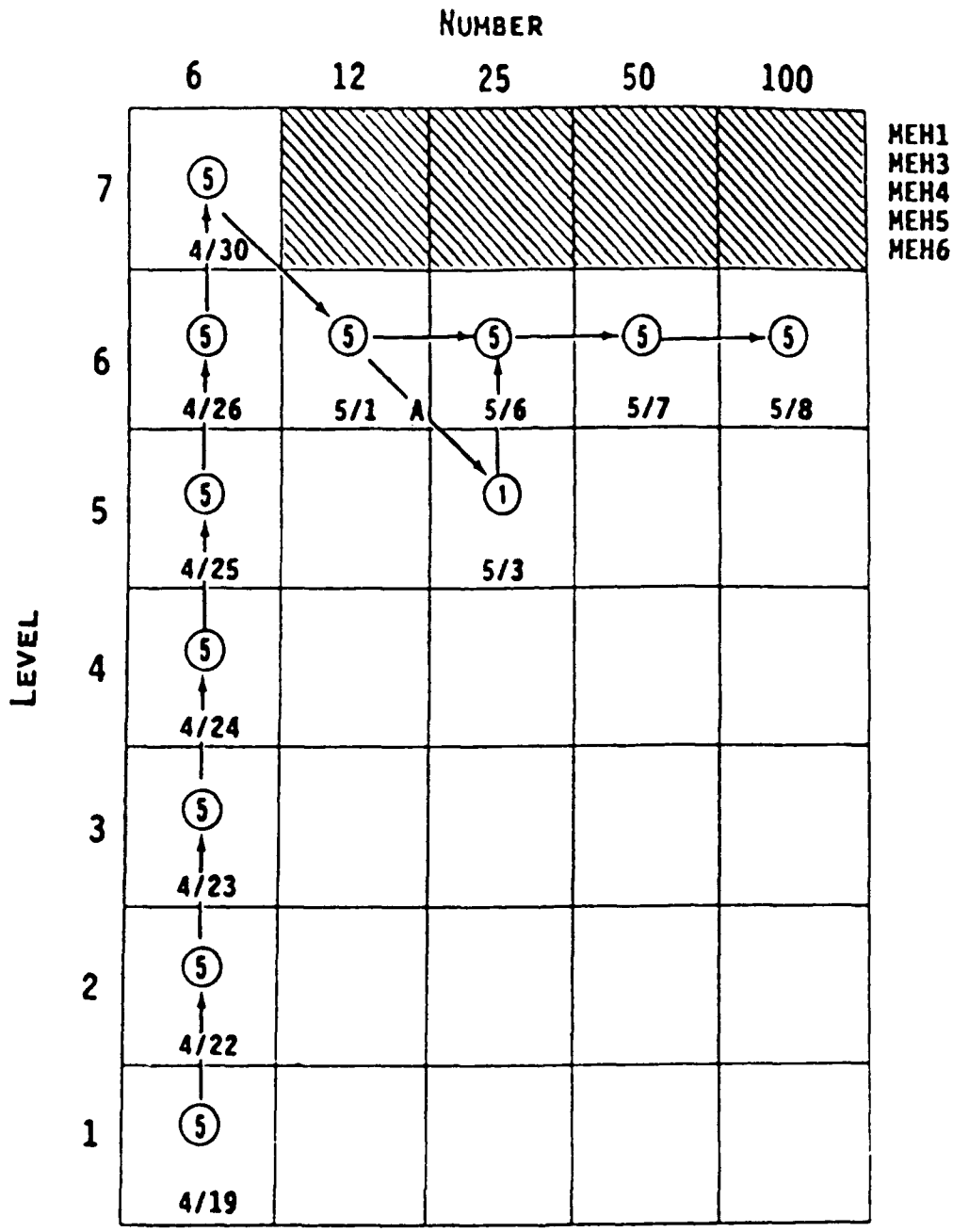


Figure E-14. GROUP MEH, APRIL-MAY 1991. 5-M Distance, Modified Muff.

a. MEH-1 had conditional auditory failure at 6/12.

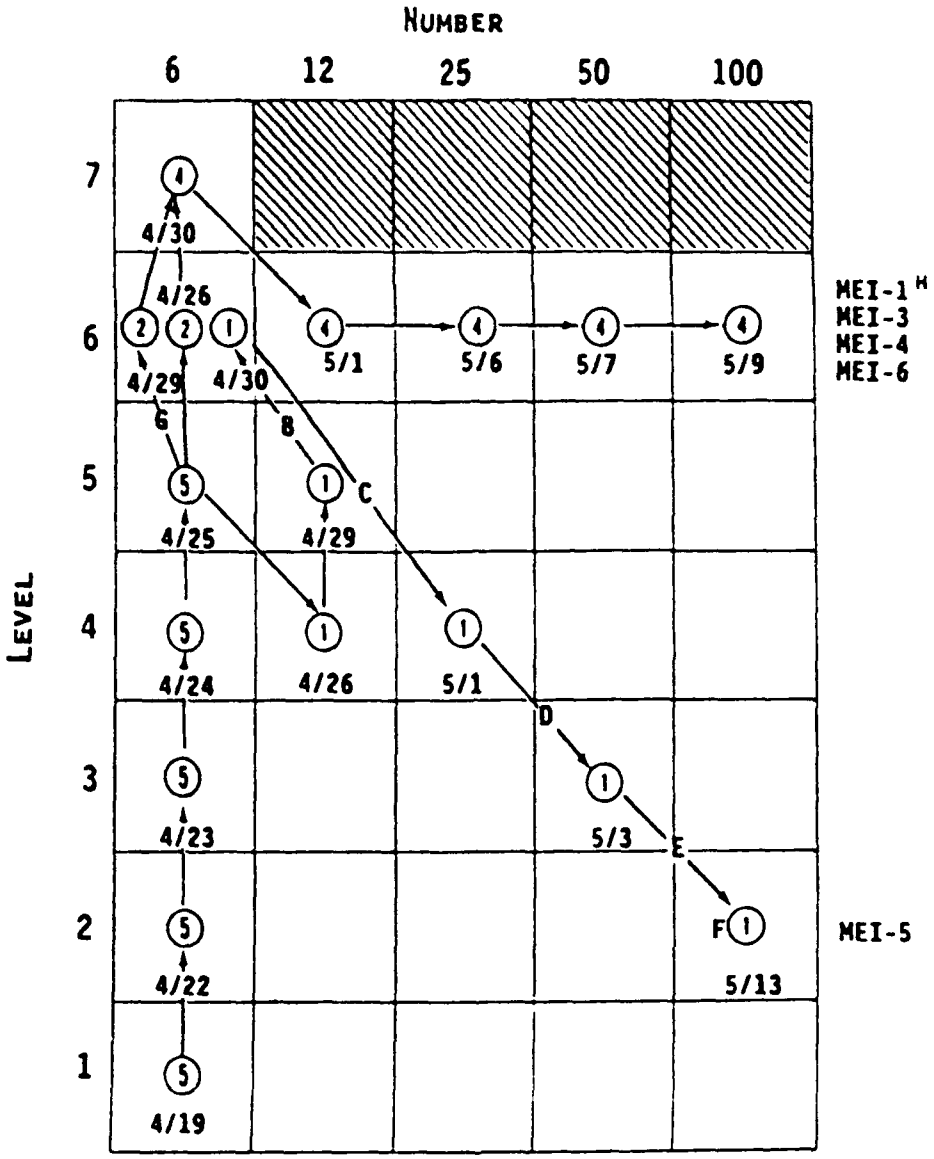


Figure E-15. GROUP MEI, APRIL-MAY 1991. 5-M Distance, Modified Muff.

a. MEI-5 had conditional auditory failure at 5/6.
b. MEI-5 was exposed to 6/6 insteat of 6/12 due to the PI's discretion.
c. MEI-5 had conditional auditory failure at 6/6.
d. MEI-5 had conditional auditory failure at 4/25.
e. MEI-5 had conditional auditory failure at 3/50.
f. MEI-5 had conditional auditory failure at 2/100. PI terminated exposure.
g. MEI-1 was delayed due to sickness.
MEI-2 was delayed due to middle ear pressure.
h. MEI-1 came off after 75 shots due to stomach cramps.

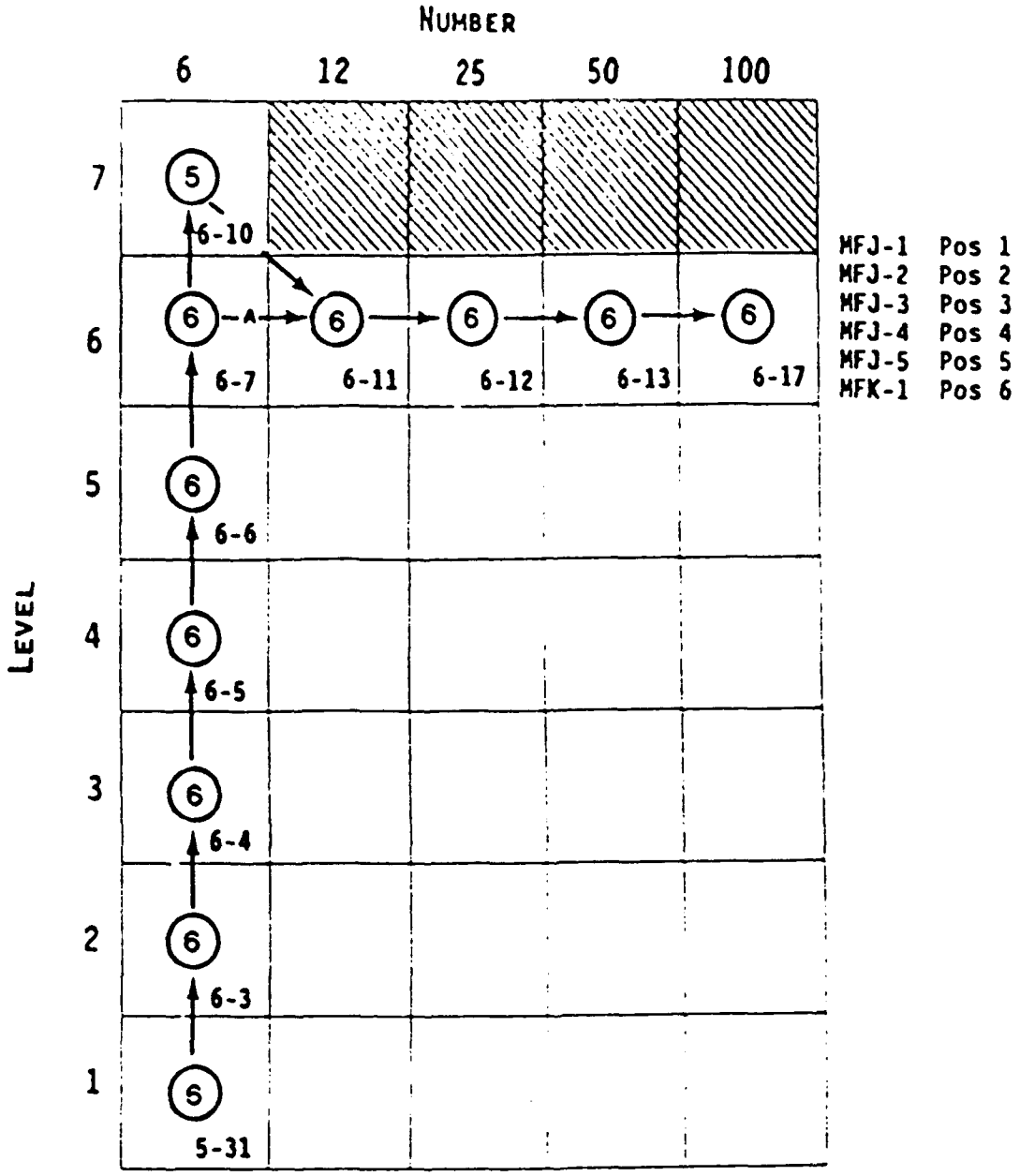


Figure E-16. GROUP MFJ, MAY-JUNE, 1991. 5-M Distance, Modified Muff.

a. MFJ-1 elected not to be exposed to level 7.

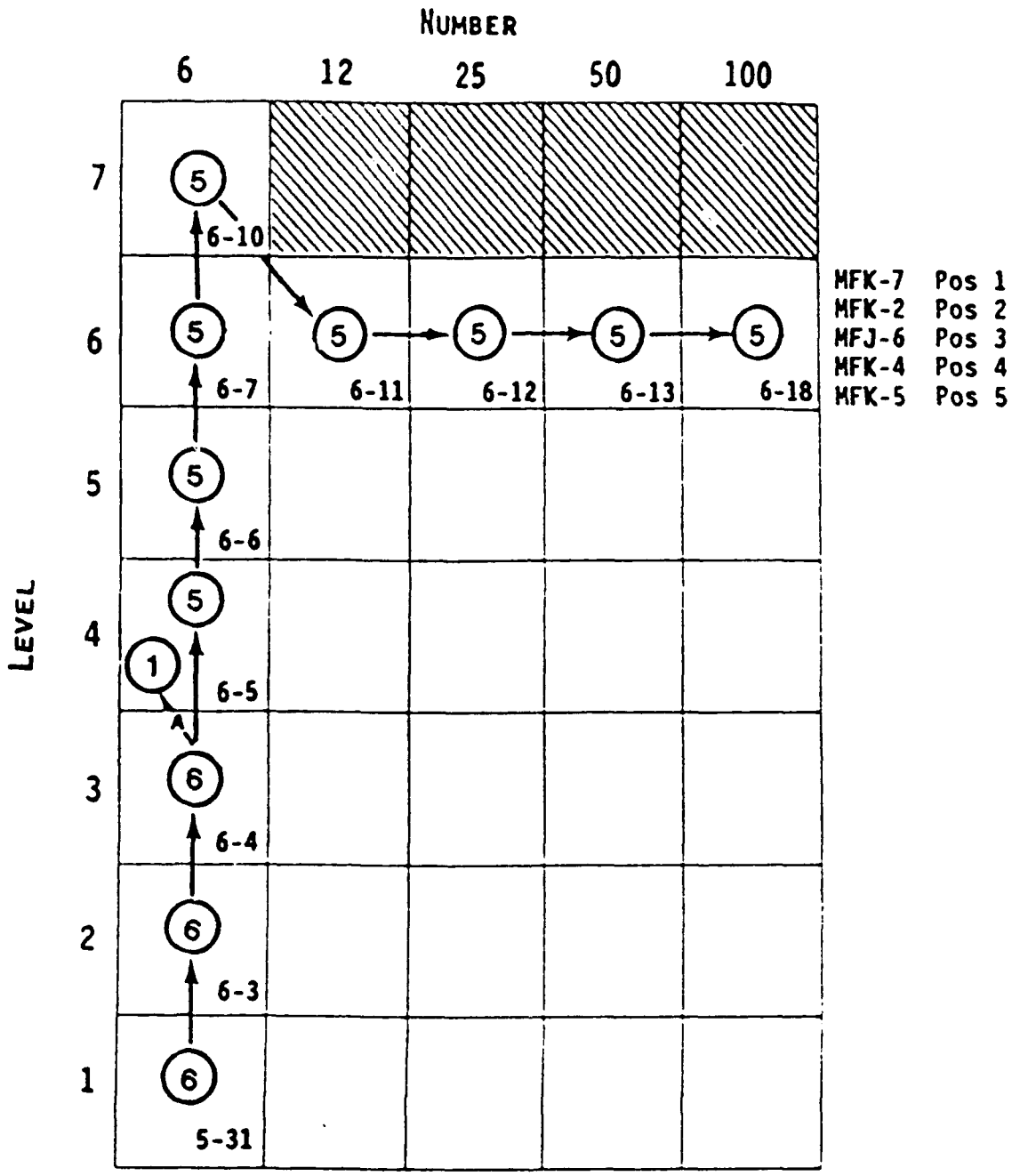


Figure E-17. GROUP MFK, MAY-JUNE, 1991. 5-M Distance, Modified Muff.

a. MFK-6 elected to stop after exposure to level 3.

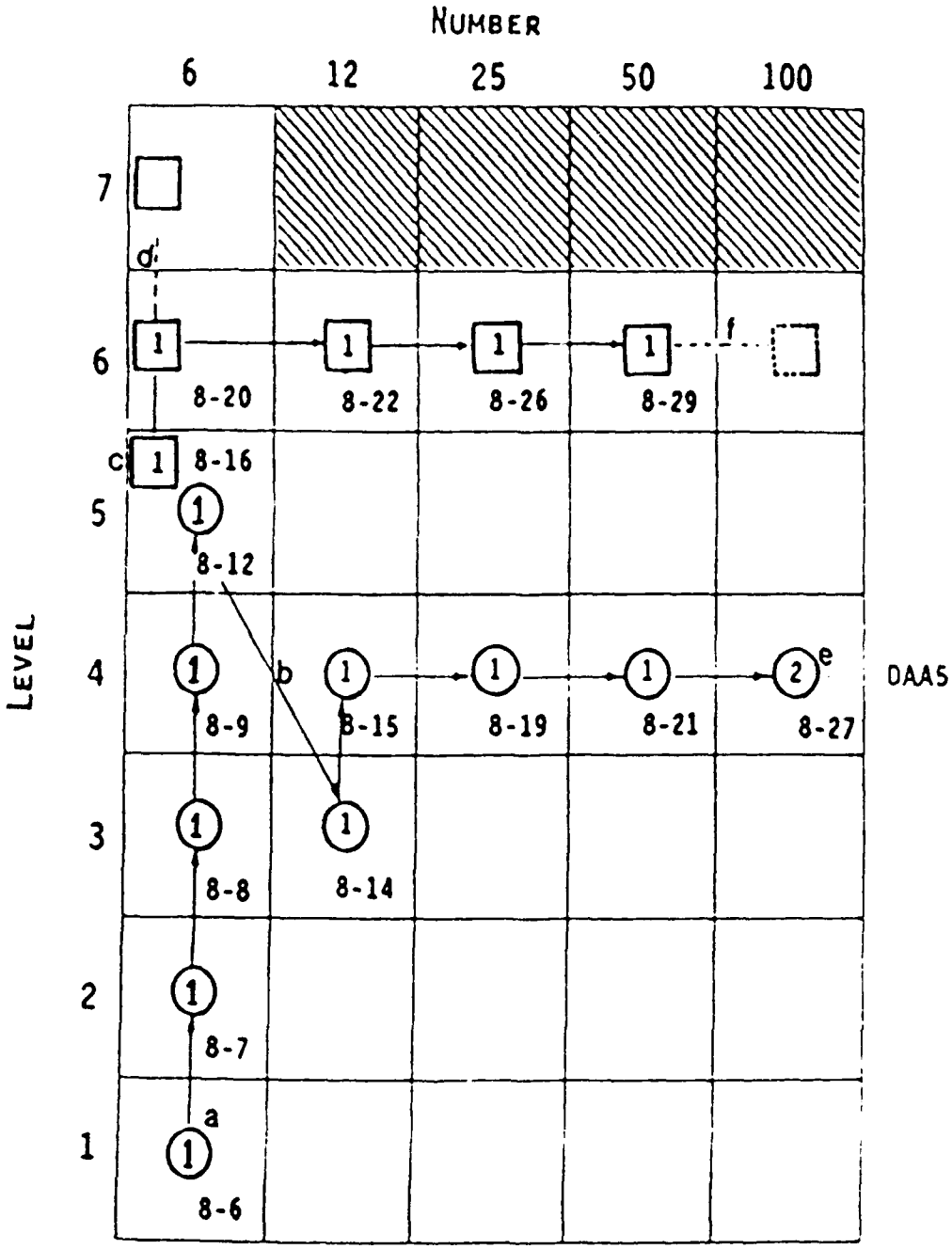


Figure E-18. SUBJECT DAA5, AUGUST 1991. 1-M Distance, Modified Muff.

a. Subject DAA5 started with subject DAB1 and DAB4.
b. Subject DAA5 was an audiometric failure after Level 5.
c. Subject DAA5 started second-level hearing protection at Level 5.
d. Subject DAA5 elected not to go to Level 7 with second-level hearing protection.
e. Subject DAA5 conditional failure after 4/100.
f. Subject DAA5 elected not to go Level 6/100 with second-level hearing protection.

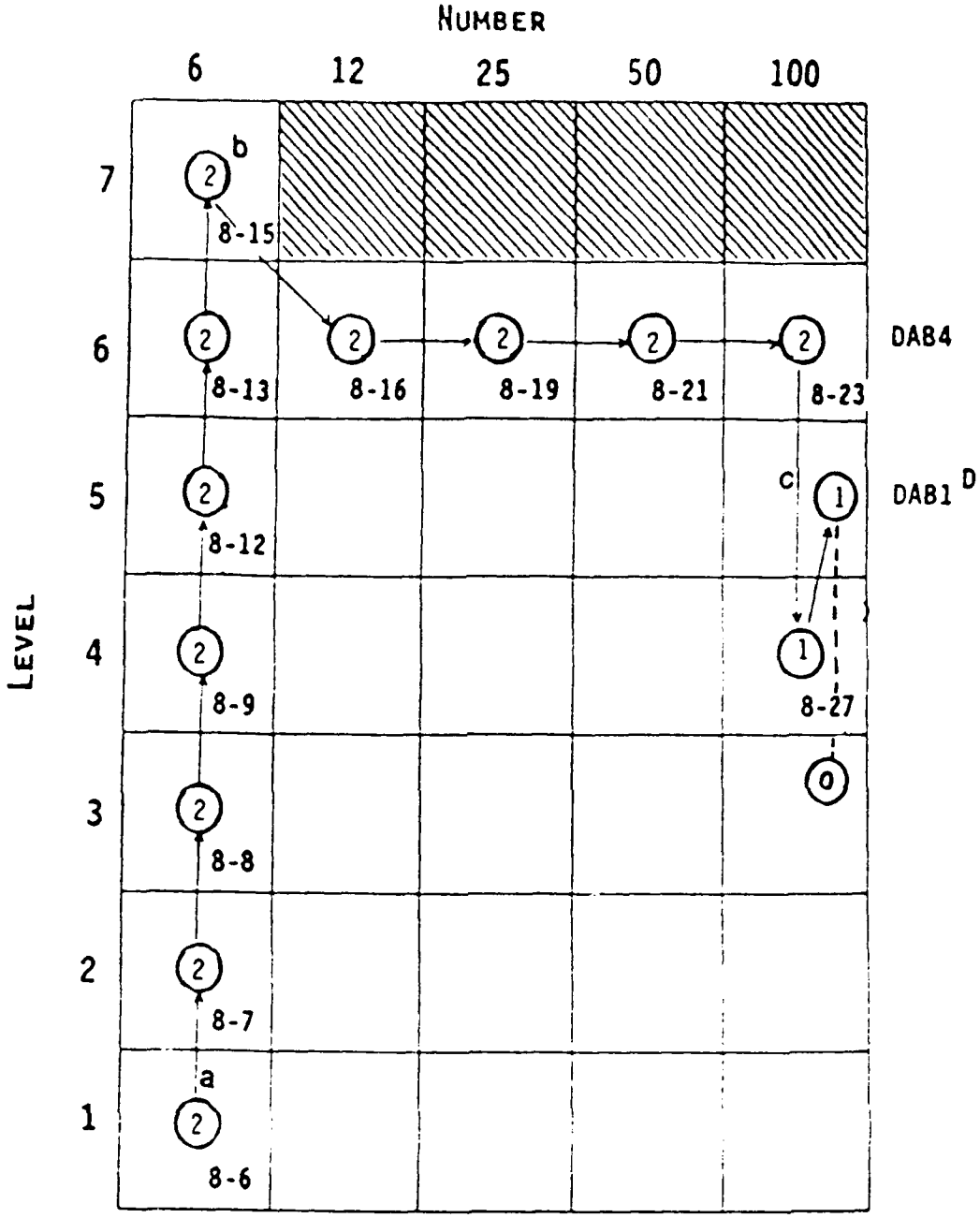


Figure E-19. GROUP DAB, AUGUST 1991. 1-M Distance, Modified Muff.

a. Subjects DAB1 and DAB4 started with subject DAA5 in order to equalize the number exposed together.
b. Group DAB combined with four subjects of group DAA.
c. Subject DAB1 had an auditory failure and a non-auditory failure after Level 6/100.
d. Subject DAB1 had an auditory failure after Level 5/100.

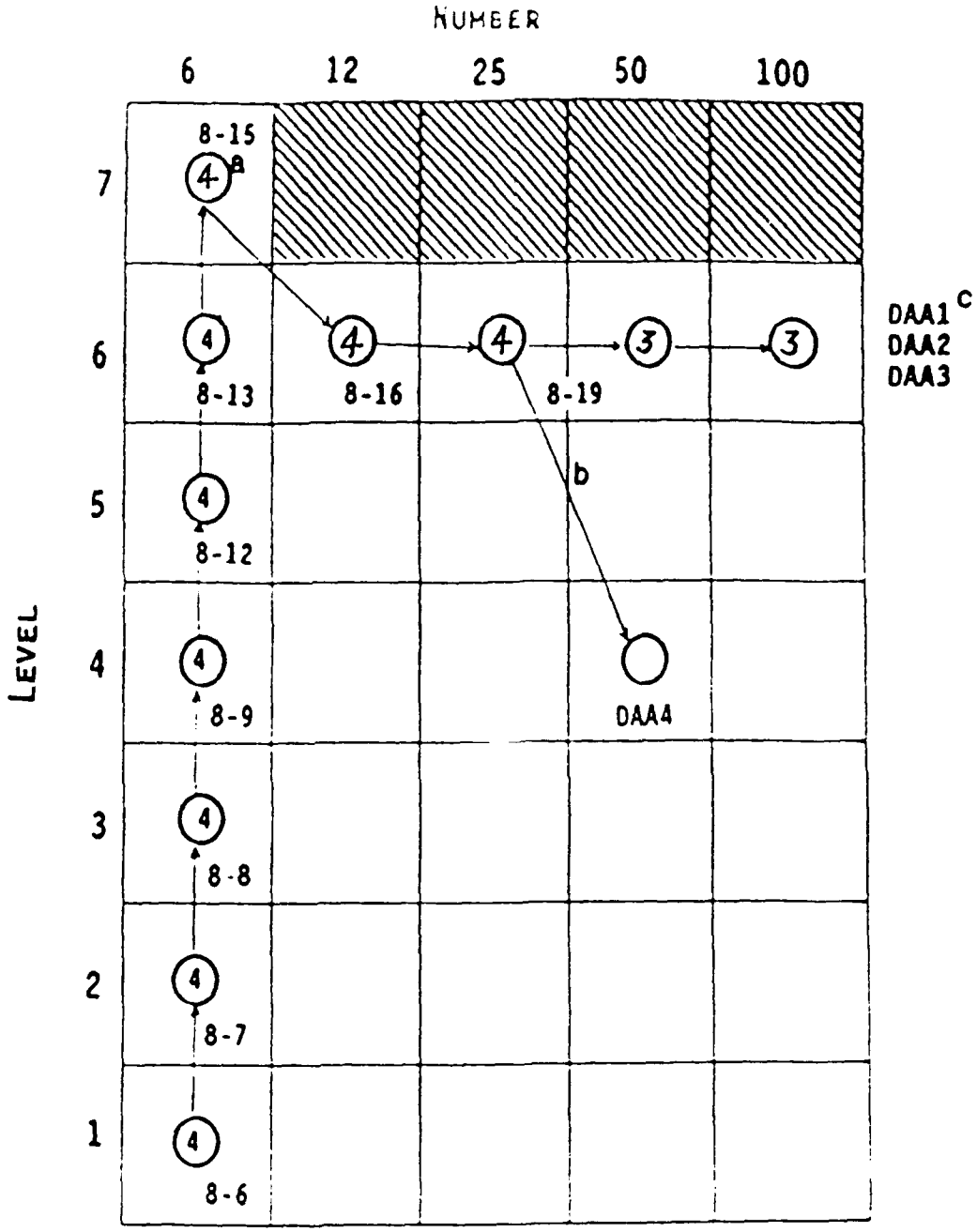


Figure E-20. GROUP DAA, AUGUST 1991. 1-M Distance, Modified Muff.

a. Group DAA combined with two subjects of Group DAB.
b. Subject DAA4, an auditory failure after Level 6/25, not allowed by the PI to continue because of delayed growth of the TTS.
c. Subject DAA1, a conditional failure after Level 6/100.

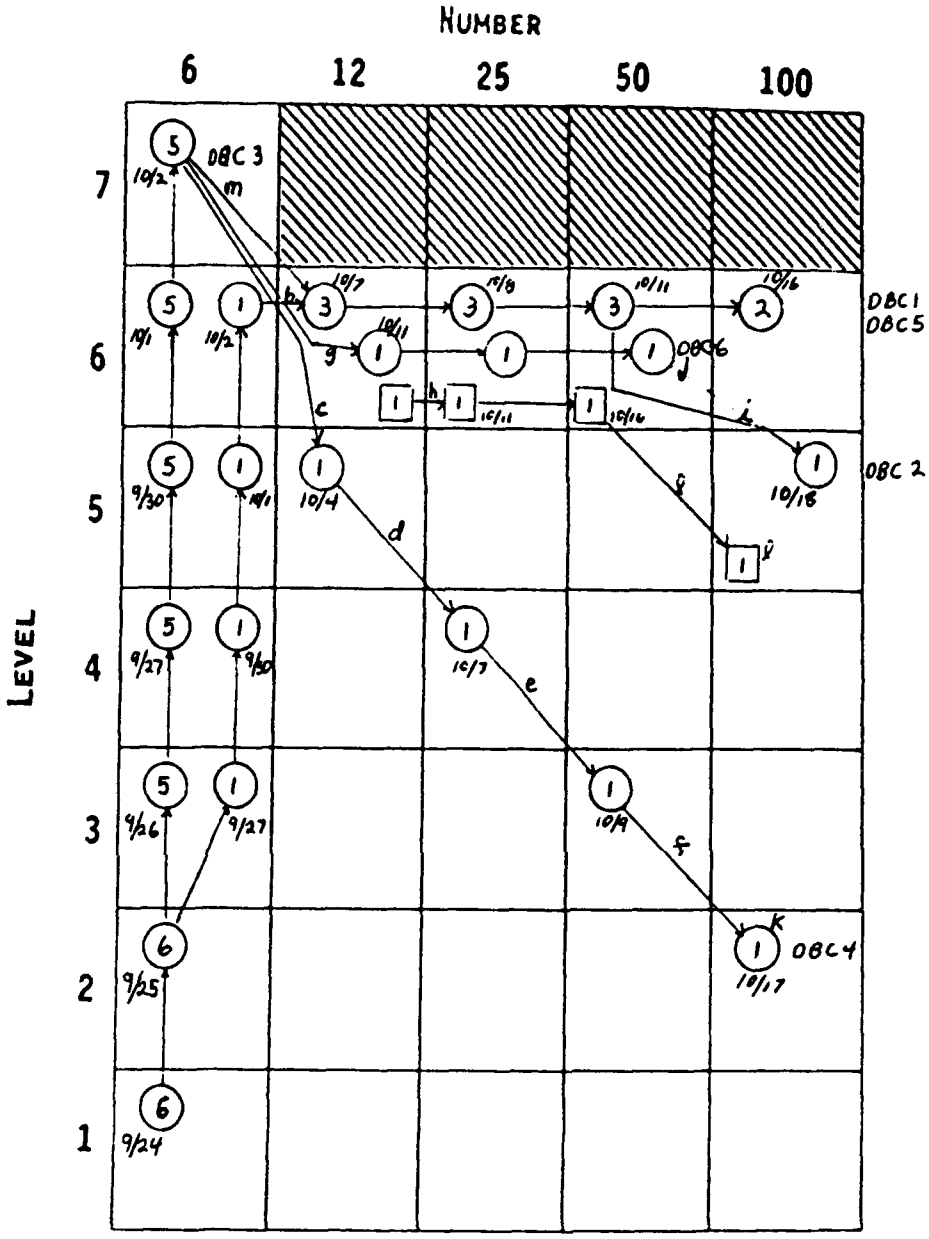


Figure E-21. GROUP DBC, SEPTEMBER-OCTOBER 1991. 1-M Distance, Modified Muff.

a. Subject DBC1 delayed due to cold that elevated hearing.
b. Subject DBC1 did not meet his baseline prior to 7/6. This exposure was delayed and the subject joined his group for 6/12.
c. Subject DBC4 was an auditory failure after 7/6.
d. Subject DBC4 was a conditional failure after 5/12.
e. Subject DBC4 was a conditional failure after 4/25.
f. Subject DBC4 was a conditional failure after 3/50.
g. Subject DBC6 was unable to meet his baseline on 10/4, 10/7, 10/8, and 10/9
h. Subject started second-level hearing protection at 6/12.
i. Subject DBC2 conditional failure after 6/50. Also, was a conditional failure at 5/100
j. Subject DBC6 suffered a loosening of an impacted wisdom tooth after shot 14 of Level 6/50. He came off the pad after shot 17. The medical monitor dropped him from further exposure.
k. Subject DBC4 was exposed to 2/100 and was a conditional failure.
l. Subject DBC4 was a conditional failure with second-level hearing protection after being exposed to 6/50 then after 5/100.
m. Subject DBC3 elected to stop further exposure and did not go to 6/12 on 17 October He was sick until 17 October with sore chest cage.

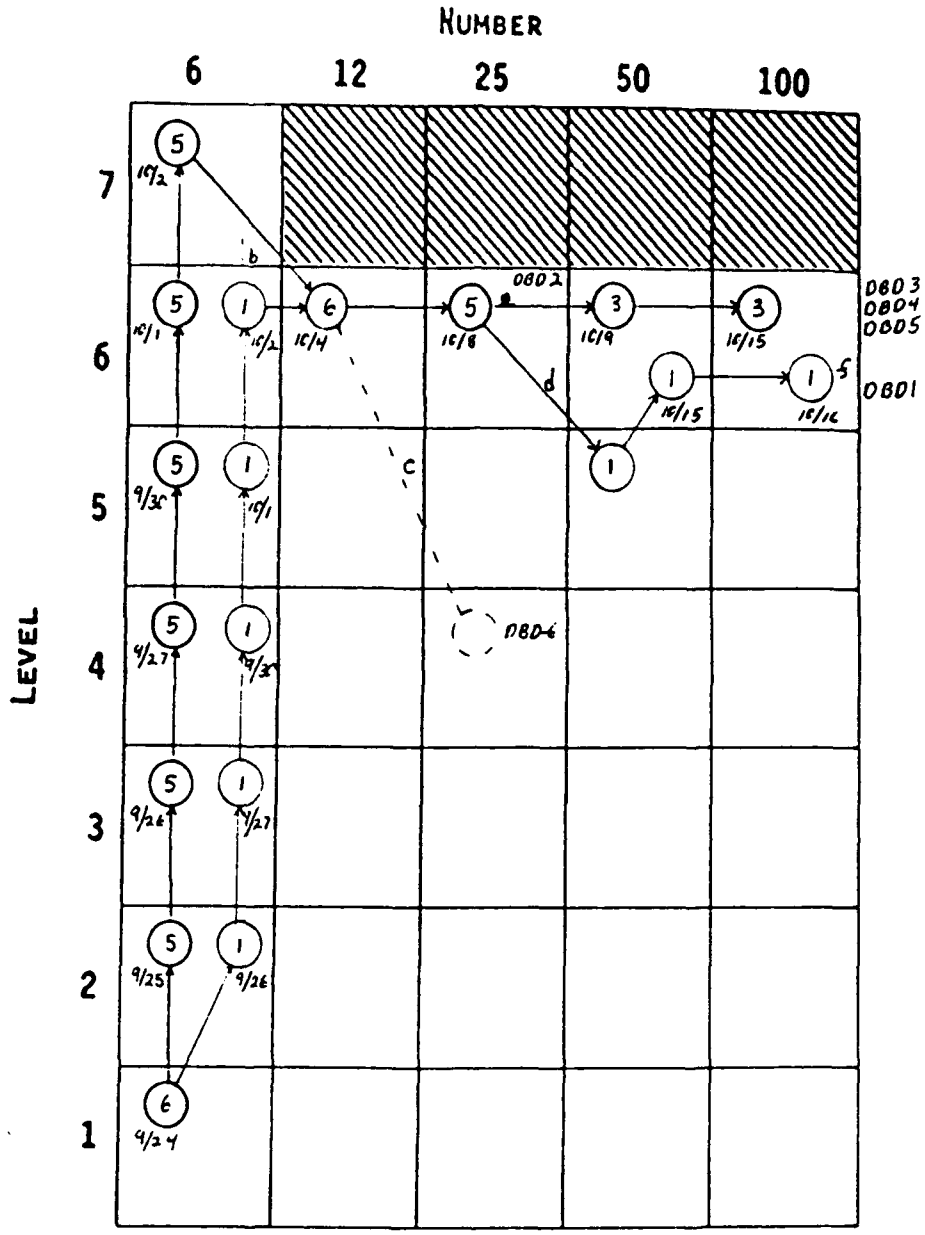


Figure E-22. GROUP DBD, SEPTEMBER-OCTOBER 1991. 1-M Distance, Modified Muff.

a. Subject DBD1 delayed because he could not get within his baseline.

b. Subject DBD1 did not meet his baseline for the 7/6 exposure. This exposure was delayed and the subject put into his group at Level 6.

c. Subject DBD6 was a failure after 6/12. Subject also had hematoma on right tympanic membrane that delayed testing. While hematoma recovered by 16 October, Medical Monitor elected to drop subject from further exposure.

d. Subject DBD1 conditional failure after 6/25. Passed 5/50 and 6/50.

e. Subject DBD2 developed illness and was not exposed on 10/9. Eventually, this subject was diagnosed as having a rib fracture from playing touch football and was eliminated from further exposure.

f. Subject DBD1 conditional failure after 6/100.

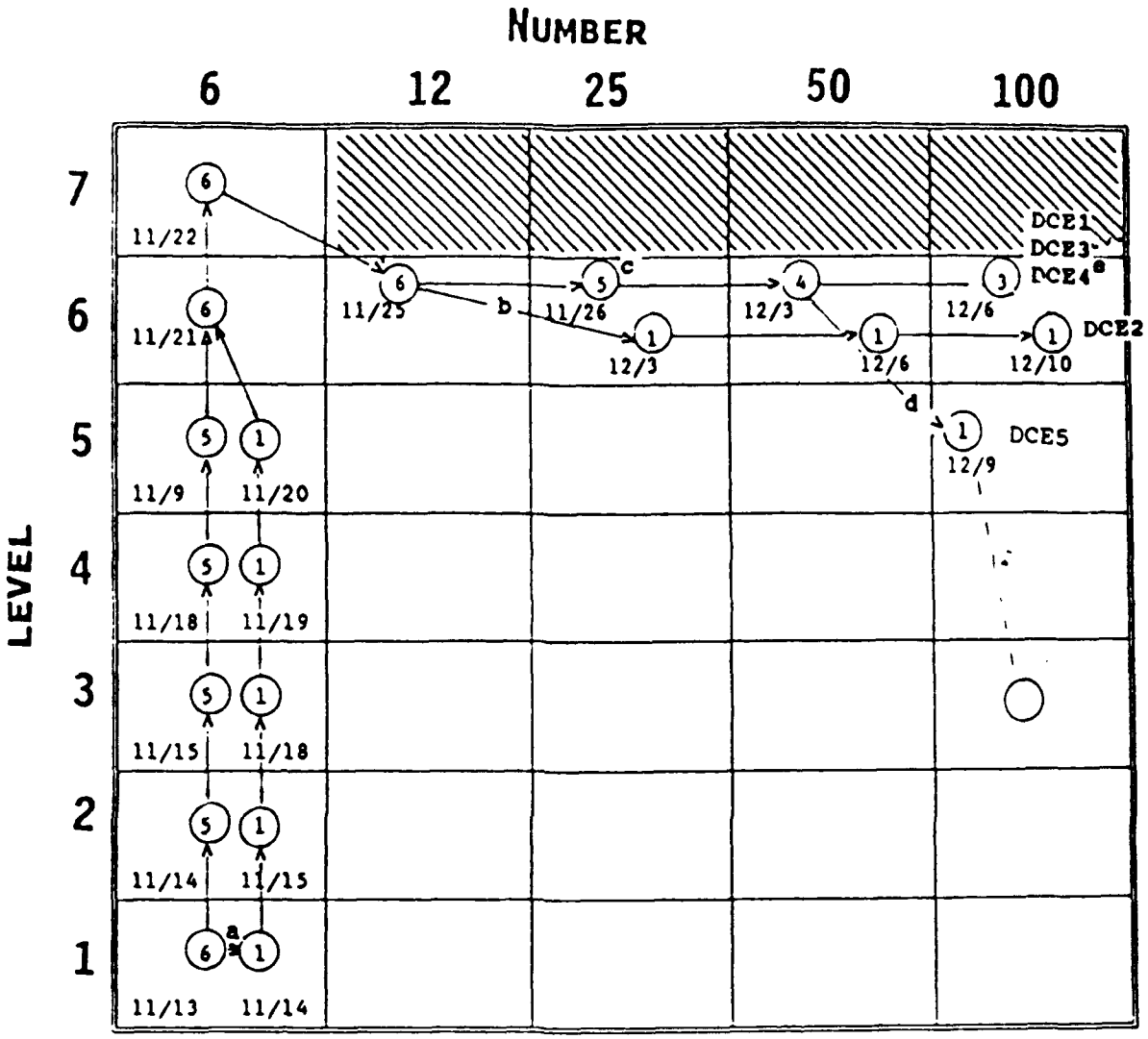


Figure E-23. GROUP DCE, NOVEMBER-DECEMBER 1991. 1-M Distance, Modified Muff.

a. Subject DCE5 conditional failure at 1/6. Repeated that condition and passed.
b. Subject DCE2 delayed because of red spot in left ear.
c. Subject DCE6 dropped from further exposure due to continuing sore throat and ear infection.
d. Subject DCE5 conditional failure at 250 Hz after 6/50.
e. Subject DCE4 conditional failure after 6/100.
f. Subject DCE5 was a failure after 5/100. Because TTs was over 40 dB, PI elected not to expose again.

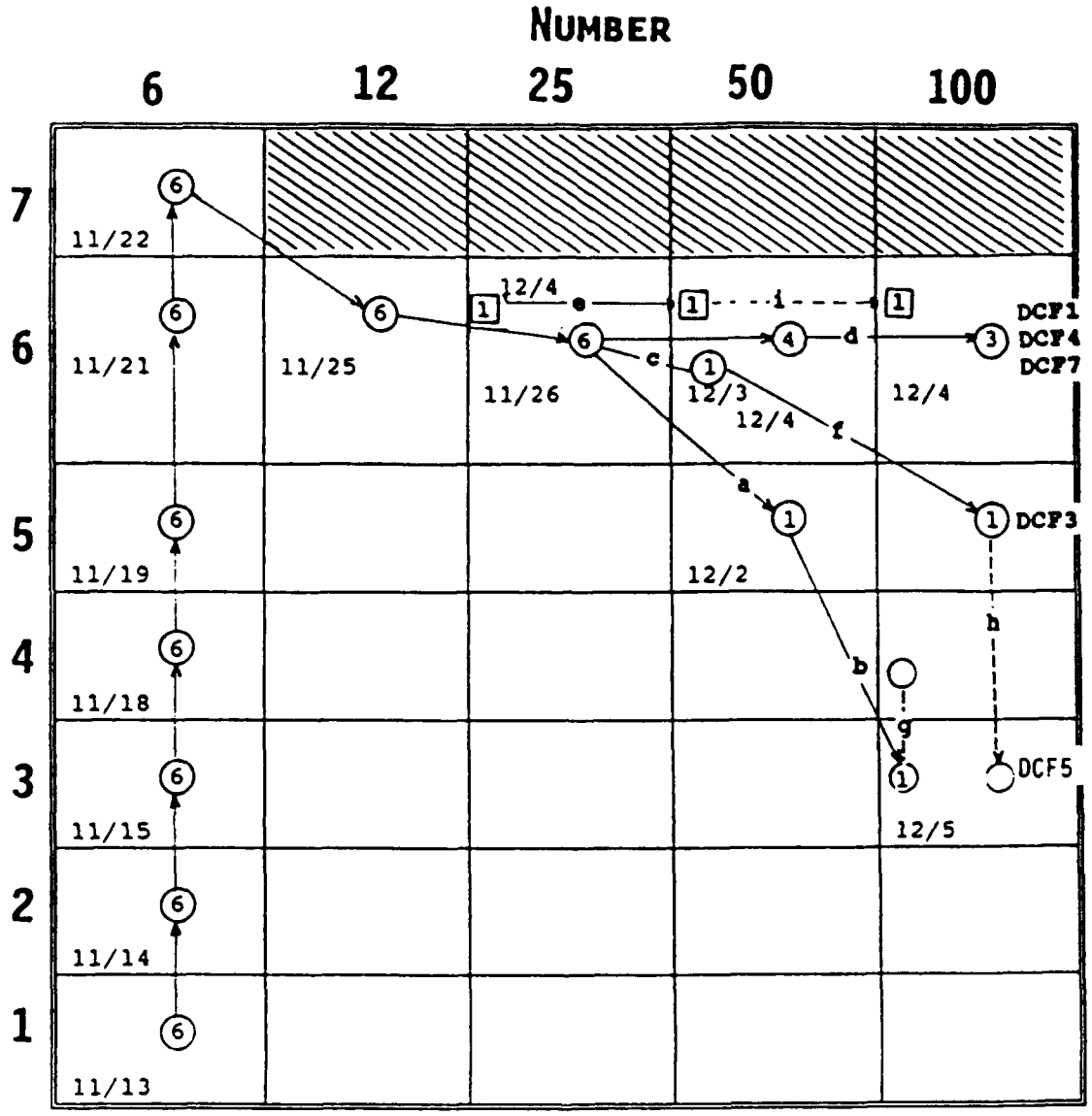


Figure E-24. GROUP DCF, NOVEMBER-DECEMBER 1991. 1-M Distance, Modified Muff.

a. Subject DCF5 conditional failure at 8 kHz after 6/25.
b. Subject DCF5 failure at 8 kHz after 5/50.
c. Subject DCF3 delayed because subject felt he was too sick to be exposed.
d. Subject DCF2 was not exposed further because he was unable to stay within his baseline.
e. Subject DCF5 started second-level hearing protection.
f. Subject DCF3 was a conditional failure after 6/50. Brought off pad at shot 39 because of ear reddening.
g. Subject DCF5 barely passed 3/100, elected not to go to 4/100.
h. Subject DCF3 failure after 5/100. PI elected not to expose further because recovery required 48 hr and TTS was more than 50 dB.
i. Subject DCF5 elected not to go to 6/100 with second-level hearing protection.

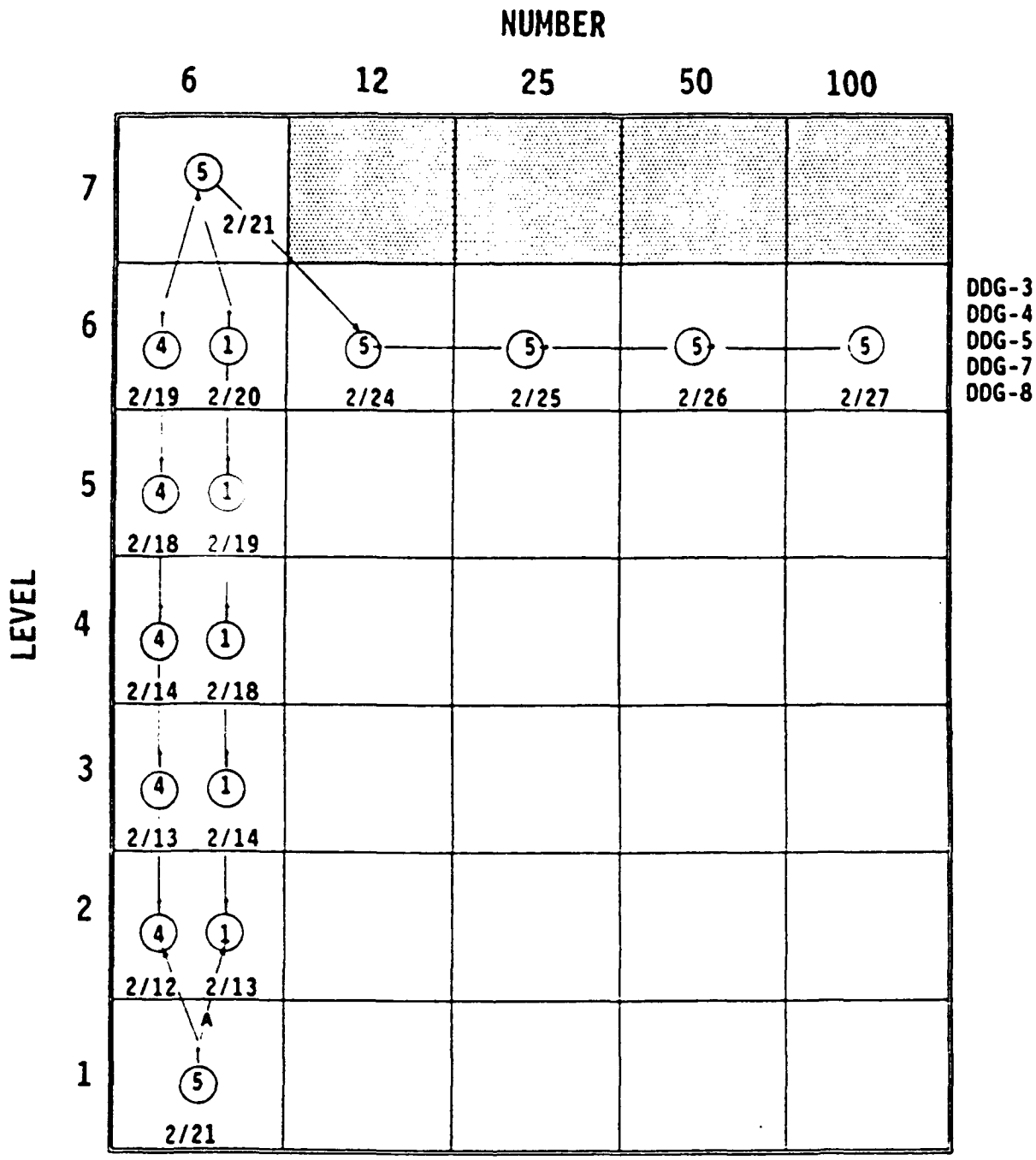


Figure E-25. GROUP DDG. JANUARY-FEBRUARY 1992. 1-M Distance. Modified Muff.

a. Subject DDG5 not exposed on 2/12/92 due to lung congestion. Started next exposure on 2/13/92.

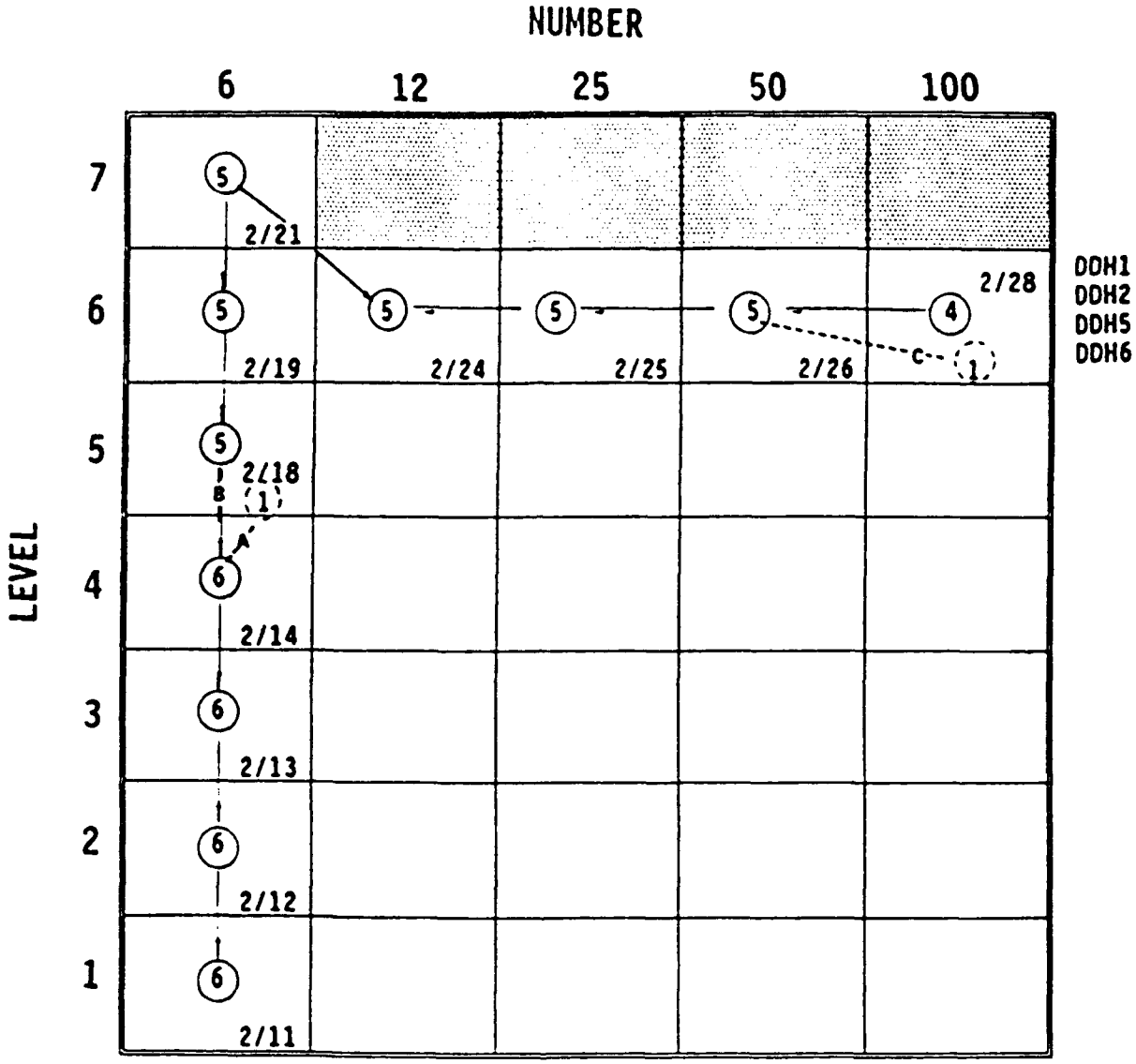


Figure E-26. GROUP DDH, JANUARY-FEBRUARY 1992. 1-M Distance, Modified Muff.

a. Subject DDH3 not exposed further because on morning of 18 February, after passing first pre-blast audiogram, did not pass second audiogram. He continued to test high at 8 kHz from that time on.

b. Subject DDH2 did not test at 2 minutes post. No signs of TTS at 20 min or 1 hour.

c. Subject DDH4 elected not to be exposed further after condition 6/50.

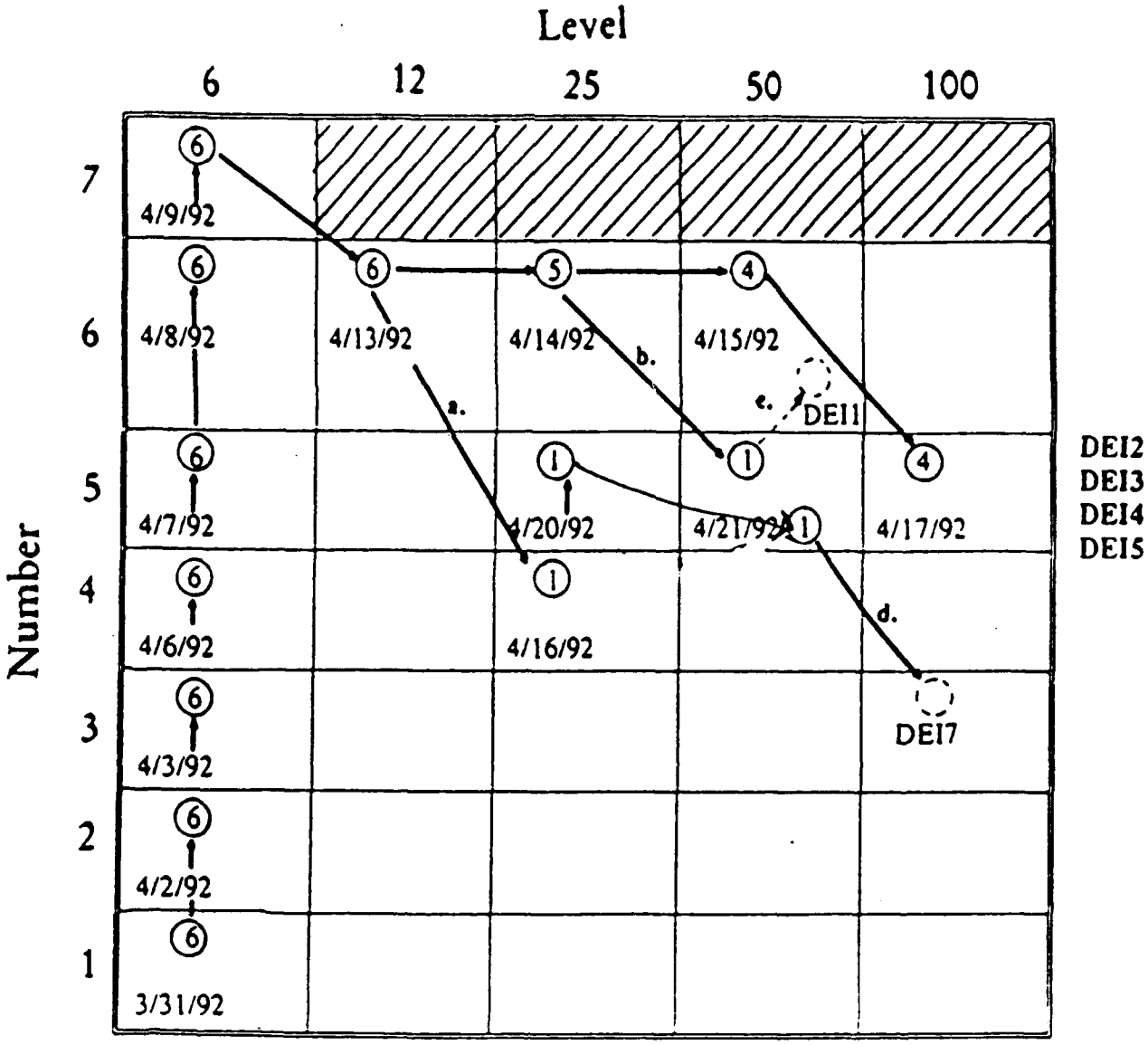


Figure E-27. GROUP DEI, MARCH-APRIL 1992. 1-M Distance, Modified Muff.

a. Subject DEI7 an auditory failure after 6/12. 30 dB at 6 kHz then recovered within 1 hr.

b. DEI1 conditional failure at 6 kHz.

c. Subjct DEI1 elected to stop exposures after successfully passing 5/50.

d. Subject DEI7 auditory failure after 5/50 at 6 kHz and 8 kHz. PI elected to stop exposure after this condition because TTS exceeded 40 dB.

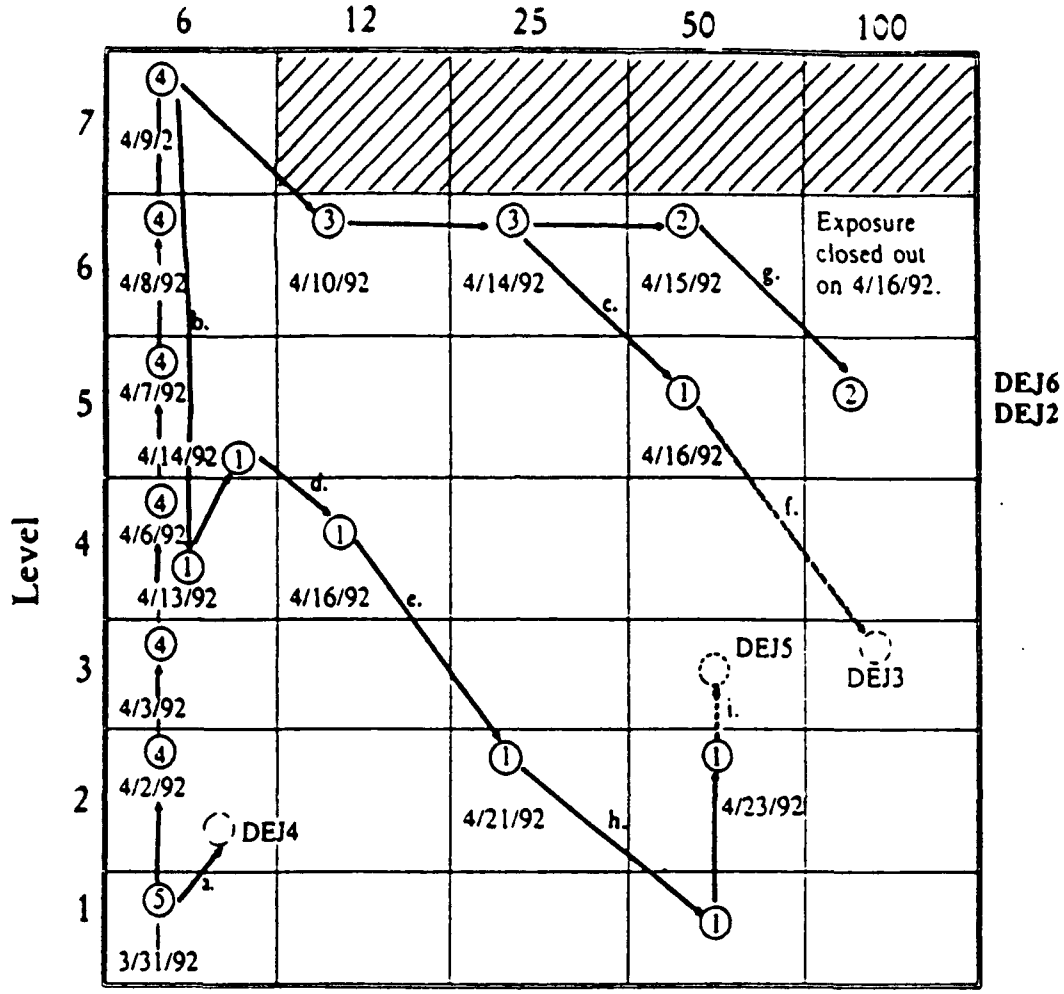


Figure E-28. GROUP DEJ, MARCH-APRIL 1992. 1-m Distance, Modified Muff.

a. Subject DEJ4 elected to stop because of personal problems. Elective failure after 1/6.
b. Subject DEJ5 an auditory failure after exposure 7/6. PI elected to start at 4/12 because of growth of TTS until the 2 hr point. Stopped after 3 shots at 4/12. Passed at this level so went to 5/6.
c. Subject DEJ3 conditional failure at 2 kHz.
d. Subject DEJ5 conditional failure after 5/7 (only 7 of 12 shots used).
e. Subject DEJ5 auditory failure after 4/12.
f. Subject DEJ3 auditory failure after 5/50 at 2 kHz. Recovered only to within 10 dB of baseline after 24 hr. Further exposure stopped.
g. Subject DEJ6 conditional failure t 8 kHz after 5/100.
h. Subject DEJ5 considered conditional failure at 4 kHz (15 dB TTS) after 2/25.
i. Subject DEJ5 elected to stop after passing 2/50.

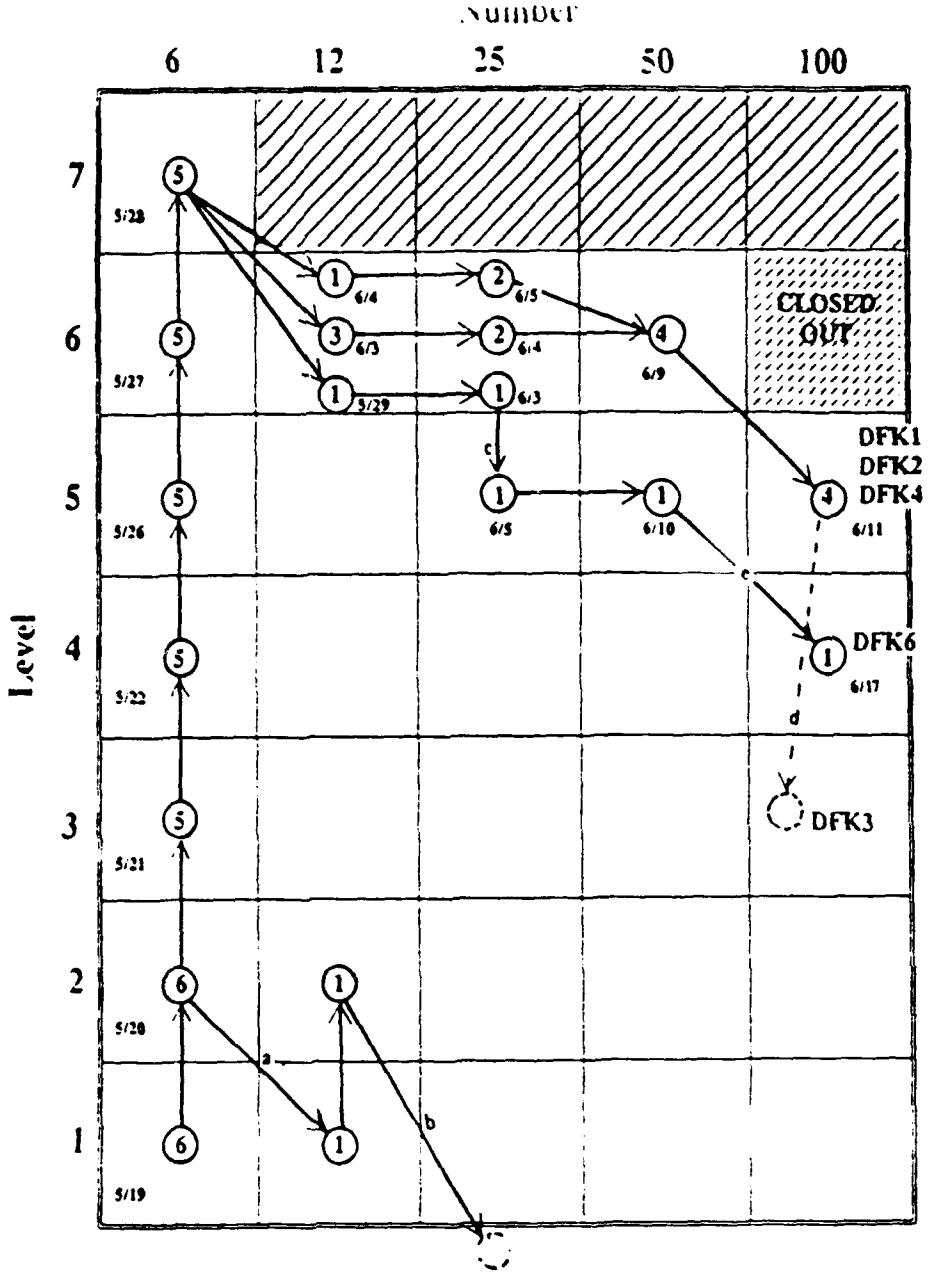


Figure E-29. GROUP DFK, MAY-JUNE 1992. 1-M Distance, Modified Muff.

a. Subject DFK5 was conditional failure at 8 kHz (20 dB) after 2/6.
b. Subject DFK5 was a failure at 2/12. Level 1 protection stopped.
c. Subject DFK6 was auditory failure after 6/25.
d. Subject DFK3 was auditory failure after 5/100. PI stopped further exposure because TTS exceeded 40 dB.
e. Subject DFK6 elected not to go to 5/100 on 11 June because he said he was not up to it. Level 5/100 was then closed out with 11 failures. Subject then went to and passed condition 4/100 on 17 June.

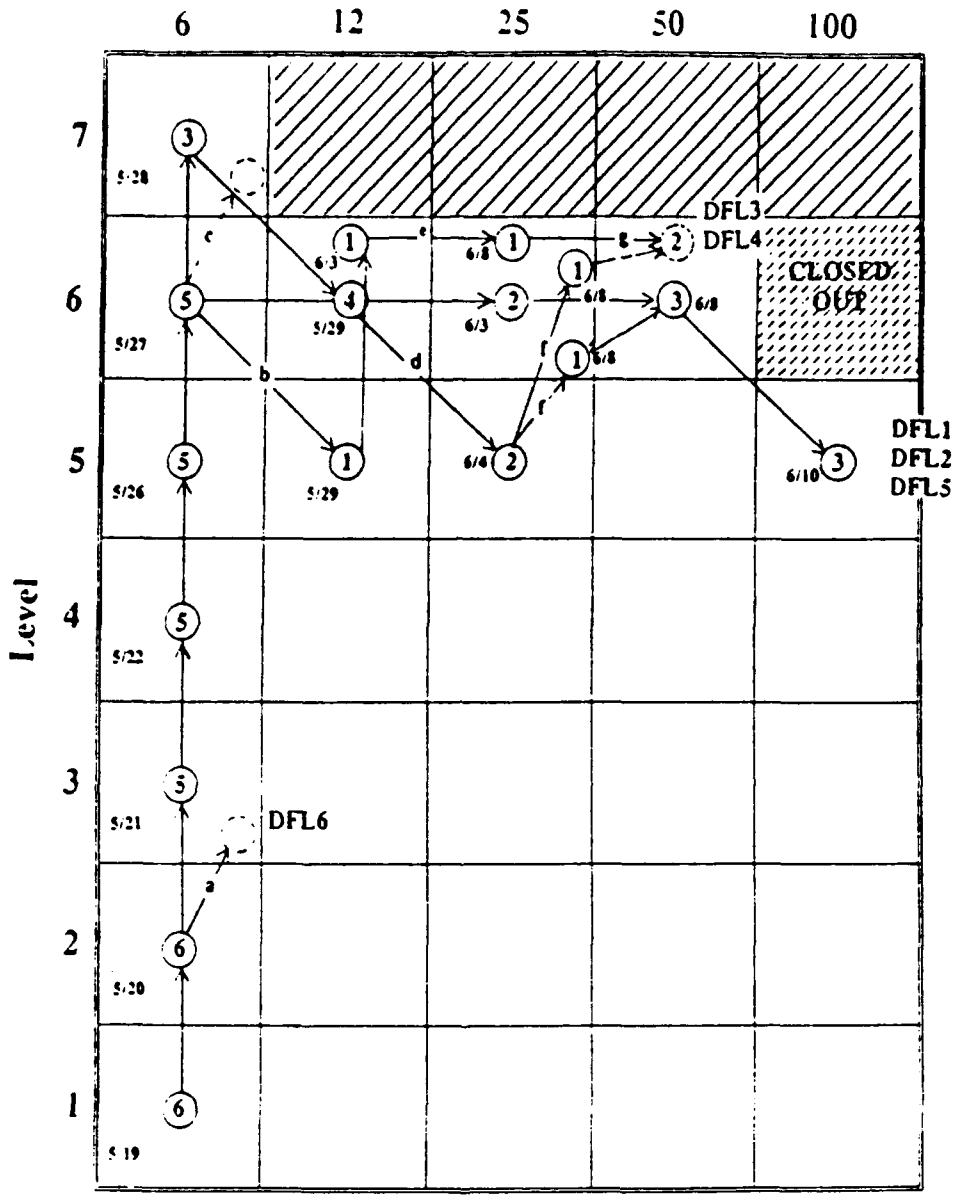


Figure E-30. GROUP DFL, MAY-JUNE 1992. 1-M Distance, Modified Muff.

a. Subject DFL6 elected to quit study because of marital considerations.
b. Subject DFL3 conditional failure at 4 kHz (19 dB) after Level 6/6.
c. Subject DFL4 elected not to be exposed to Level 7/6.
d. Subjects DFL1 and DFL4 conditional failures after conation 6/12.
. Subject DFL3 passed condition 6/12, clearing conditional faille at 6/6.
f. Subjects DFL1 and DFL4 exposed to condition 6/25 and passed, clearing conditional failures at 6/12.
g. Subjects DFL3 and DFL4 elective failures in that both declined to go to condition 6/50 or even 5/50.

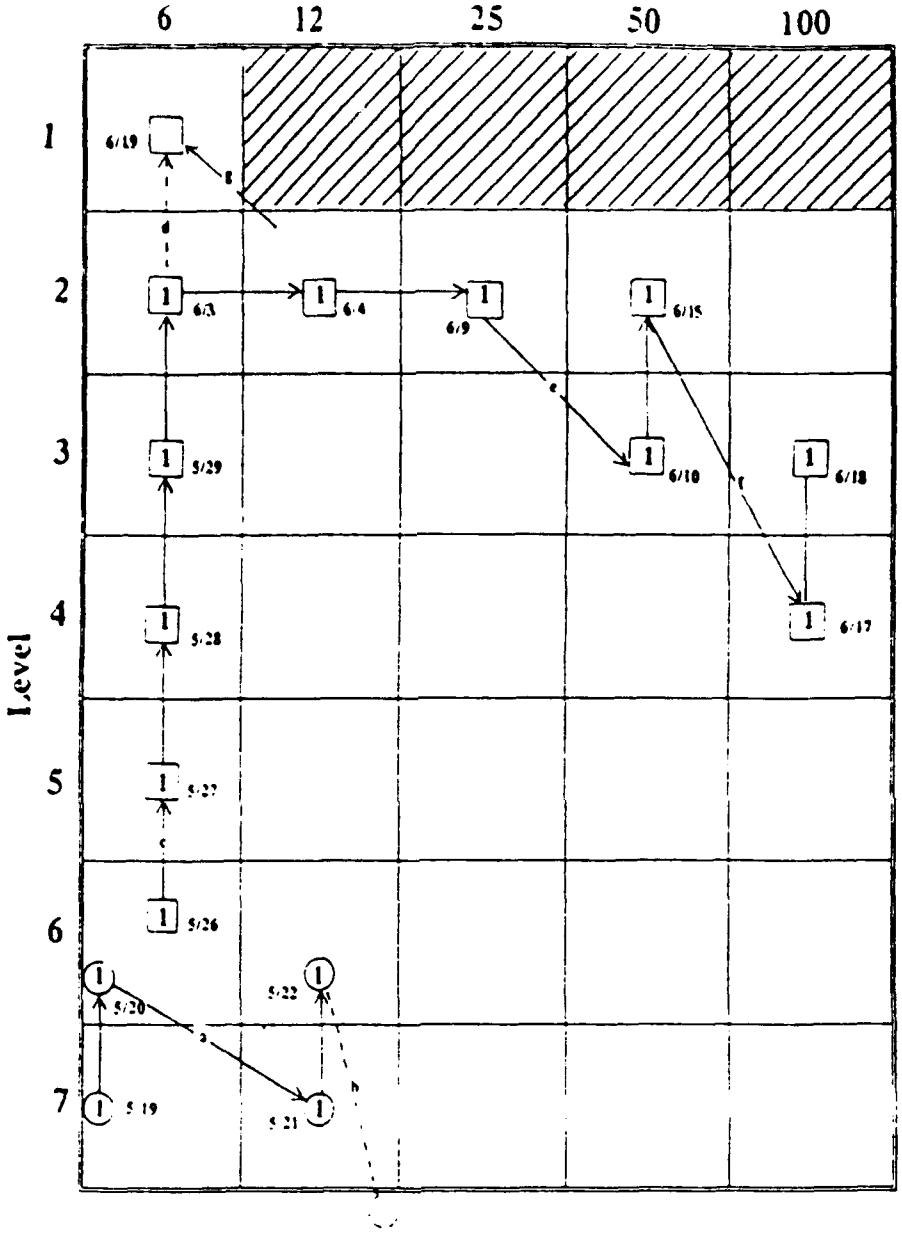


Figure E-31. SUBJECT DFK-5, MAY-JUNE 1992, 1-M Distance, Modified Muff.

a. DFK-5 was a conditional auditory failure at 8kHz (20 dB) after 6/2.
b. DFK-5 was an auditory failure at 2/12. First-level hearing protection stopped.
c. DFK-5 started second-level hearing protection with condition 2/6.
d. DFK-5 elected not to go to level 7 with second-level hearing protection at that time. He said he might go later.
e. DFK-5 was a conditional auditory failure after level 6/25 with second-level hearing protection.
f. DFK-5 was an auditory failure wiht second-level protection at 6/50.
g. DFK-5 elected to finish his exposures at level 7/6. He passed at that condition.

○ = First-level hearing protection.
□ = Second-level hearing protection.

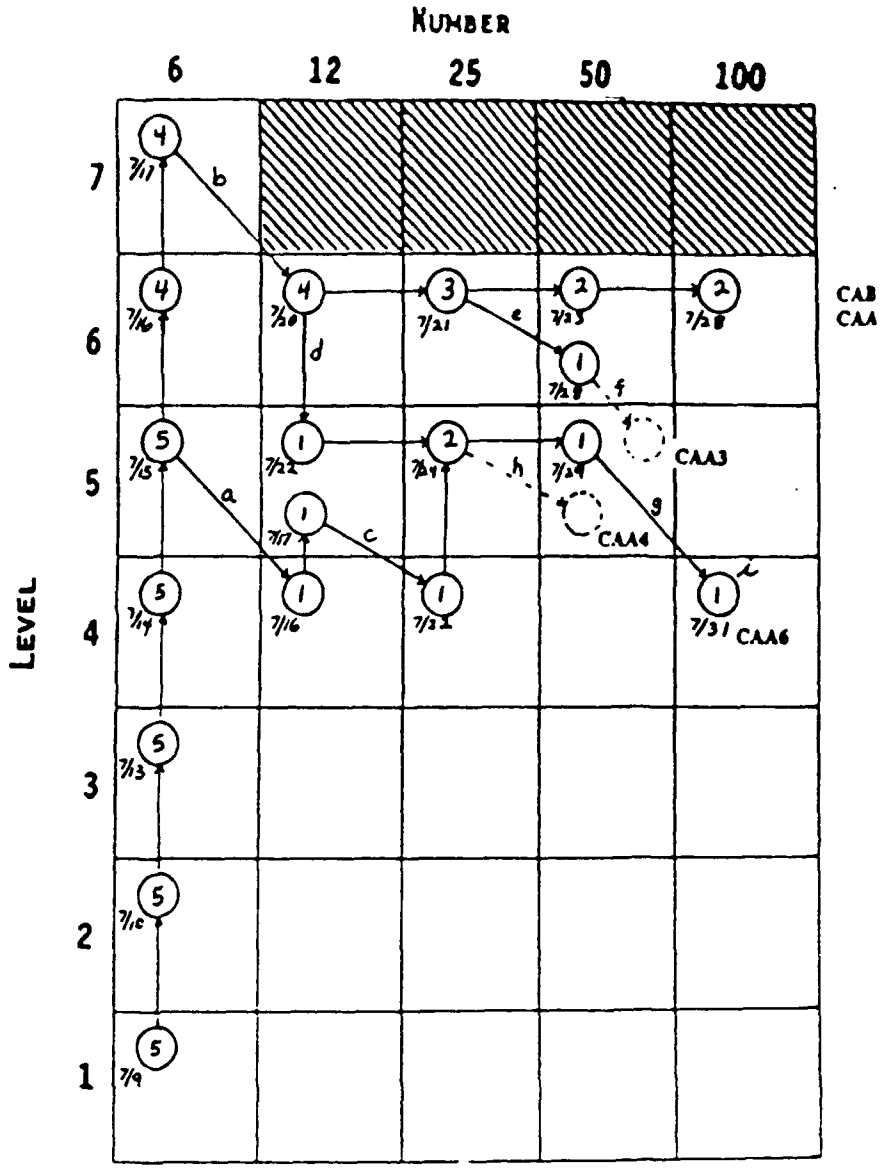


Figure E-32. GROUP CAA, JULY-AUGUST 1992, 3-M Distance, Modified Muff.

a. CAA-4 was a conditional auditory failure after 5/6 with a TTS of 23 dB at 8 kHz.
b. CAA-3 elected to stop after one shot at condition 7/6.
c. CAA-4 was a conditional auditory failure after 5/12 with at TTS of 20 dB at 8kHz.
d. CAA-6 was an auditory failure after condition 6/12 with at TTS of 25 dB at 3 kHz.
e. CAA-3 could not meet his basseline prior to his exposure to 6/50 on 23 July.
f. CAA-3 was a hard auditory failure after 6/50 with at TTS of 54 dB at 6 kHz. PI elected to stop further exposure at this point because of recovery taking longer than 24 hours.
g. CAA-6 was a conditional auditory failure after 5/50 with a TTS of 17 dB at 8 kHz.
h. CAA-4 could not meet his baseline at 8 kHz on 28, 29, and 31 July. Therefore, condition 5/50 did not occur. On 30 July, subject indicated that he wanted to quit.
i. CAA-6 was a conditional auditory failure after 4/100 with a TTS of 19 dB at 2 kHz and 18 dB at 6 kHz.

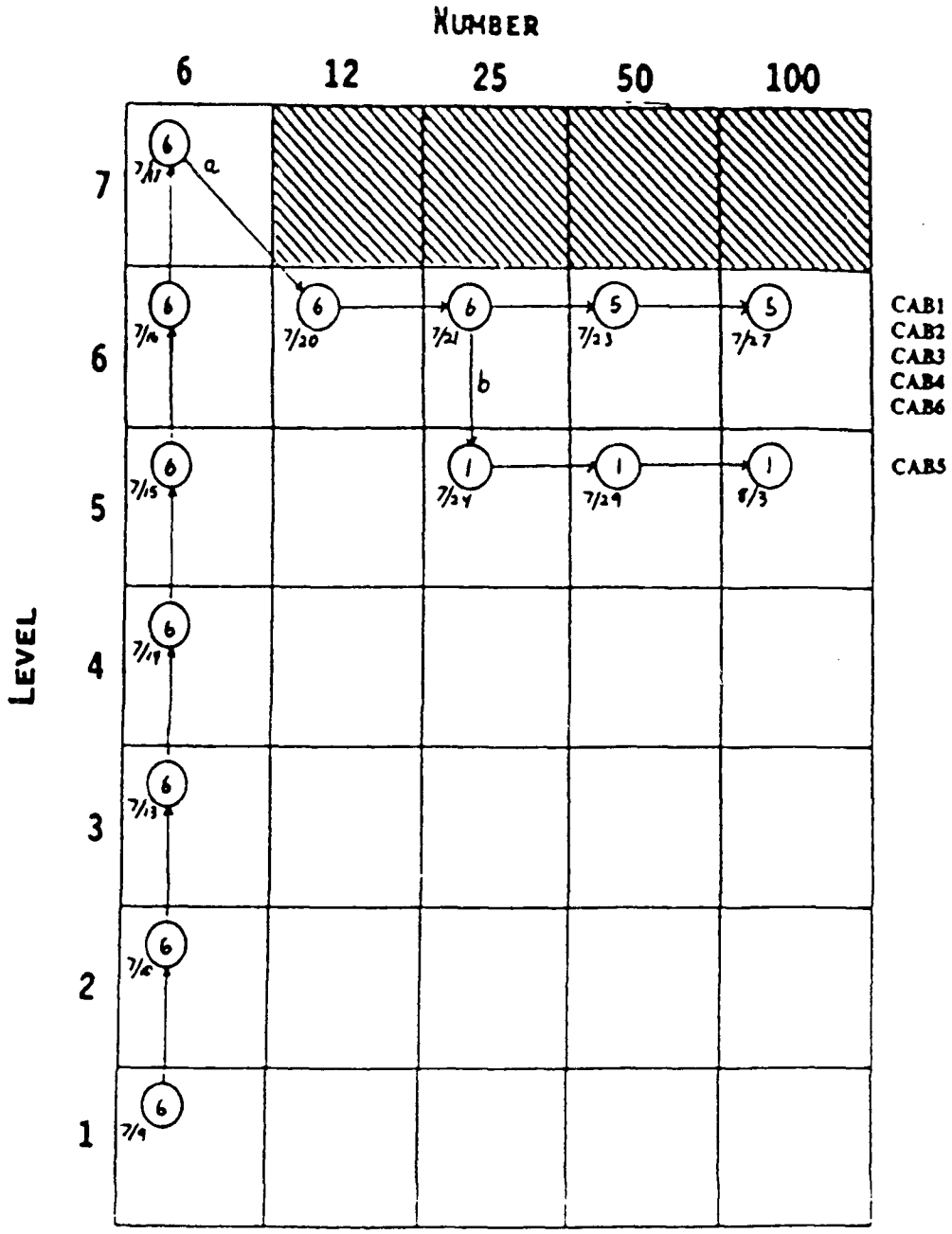


Figure E-33. GROUP CAB, JULY-AUGUST 1992, 3-M Distance, Modified Muff.

a. CAB-6 was exposed to only 1 shot and subject CAB-3 was exposed to only 2 shots at condition 7/6. Both elected to leave the pad early because of the discomfort of the level 7 shot.

b. CAB-5 was an auditory failure after 6/25 with a TTS of 36 dB at 8 kHz.

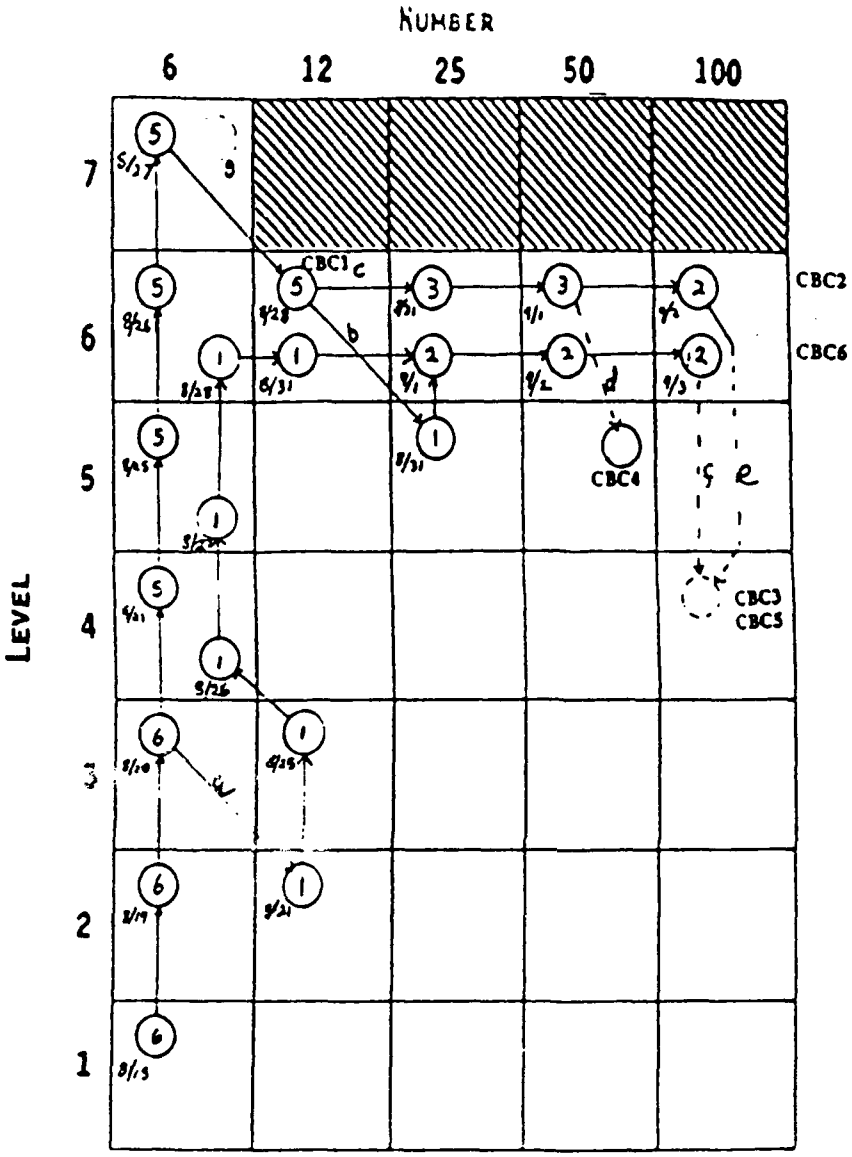


Figure E-34. GROUP CBC, AUGUST-SEPTEMBER 1992, 3-M Distance, Modified Muff.

a. CBC-6 was a conditional auditory failure after condition 3/6 with a TTS of 19 dB at 6 kHz.

b. CBC-5 was a conditional auditory failure after condition 6/12 with at TTS of 20 dB at 3 kHz.

c. CBC-1 on August 31, elected to quit further exposure because of overall anxiety about his well being.

d. DBD4 was an auditory failure after condition 6/50 with a TTS of 44 dB at 3 kHz and 34 dB at 4 kHz. This subject was not exposed further because his hearing at 3 Khz tool longer that 24 hours to return to normal.

e. CBC-3 was an auditory failure after condition 6/100 with a TTS of 45 dB at 8 kHz. He recovered to his baseline in 48 hrs so further exposure was stopped because his recovery was taking longer than 24 hrs. His TTS at 24 hr was 10 dB at 8 kHz.

f. CBC-5 was an auditory failure after condition 6/100 with a TTS of 26 dB at 4 kHz at the 2 minute test and a TTS of 42 dB at 4 kHz at the 20 minute test. While recovery was complete at 24 hr, the fact that the TTS grew with time and was more that 40 dB resulted in the PI terminating further exposure.

g. DBD-6, after passing condition 6/100, was given the option of being exposed to condition 7/6. He declined to be exposed to this condition; therefore, he should be considered an elective failure for condition 7/6.

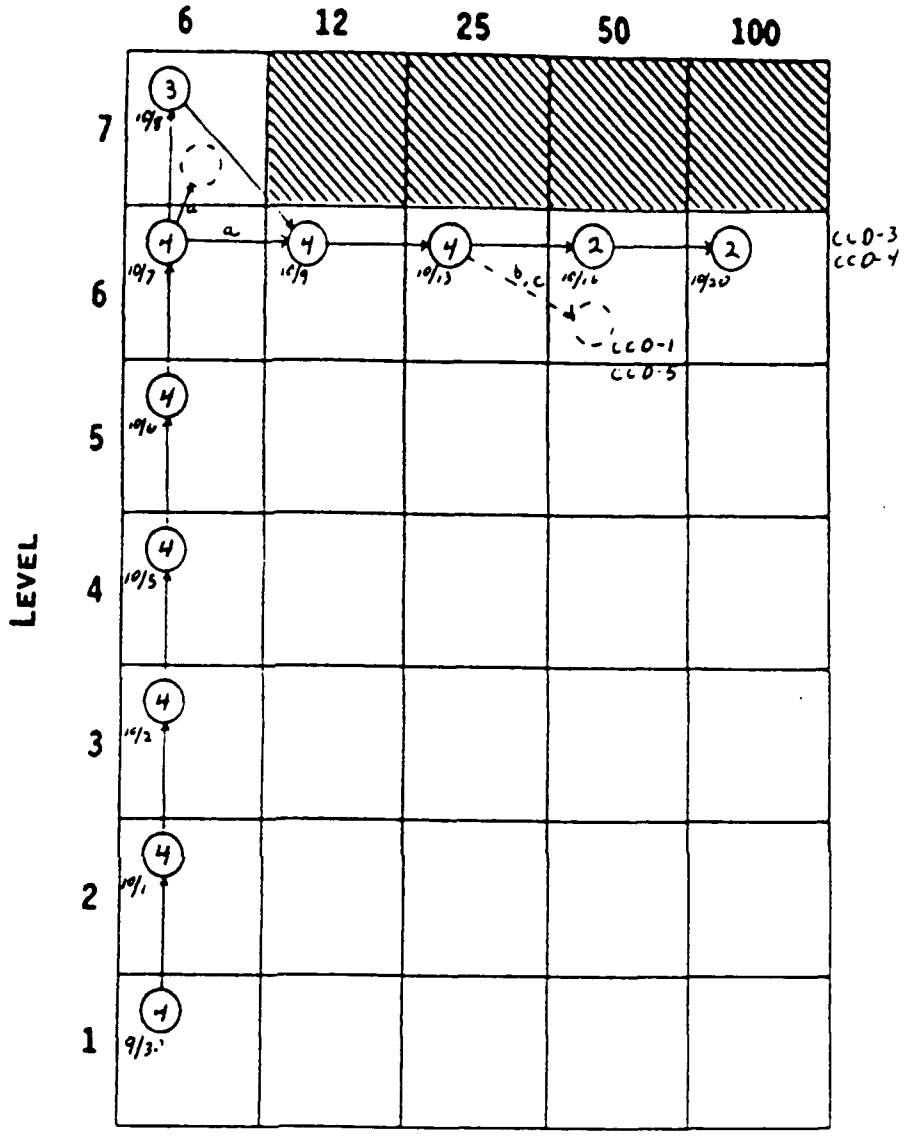


Figure E-35. GROUP CCD,SEPTEMBER-OCTOBER 1992, 3-M Distance, Modified Muff.

a. CCD-1 did not go to level 7/6 on 8 October because of stomach cramps. He elected not to go to 7/6 on 20 October.

b. CCD-5 elected to stop further exposures after condition 6/25 due to personal problems.

c. CCD-1 elected to stop further exposures after condition 6/25.

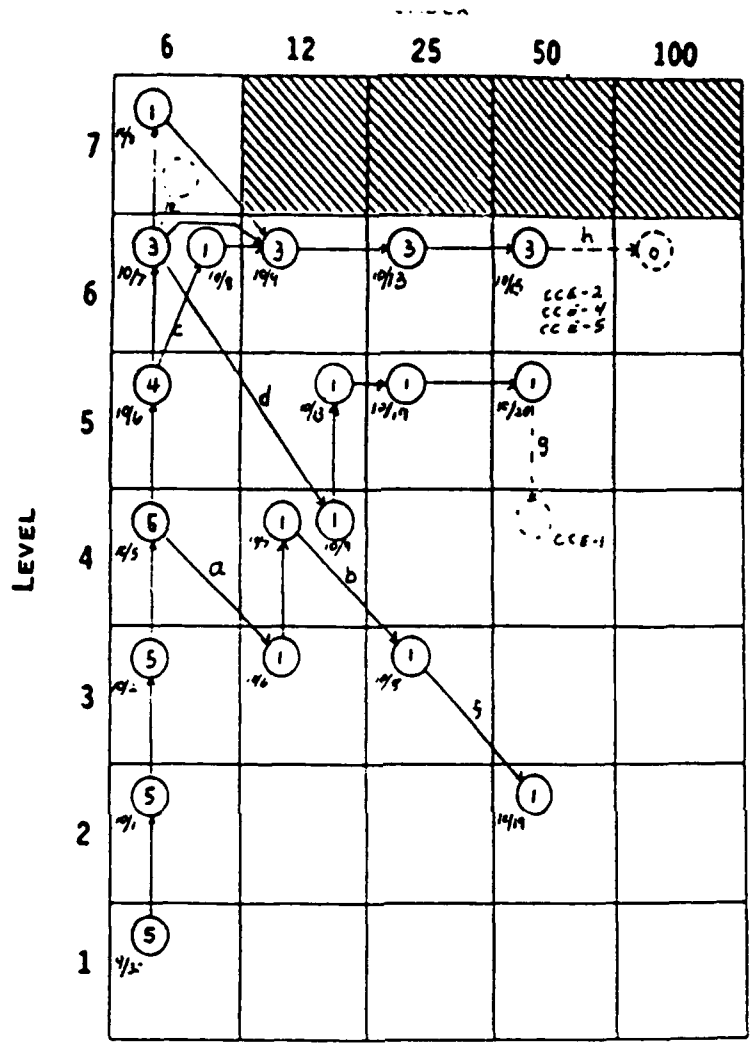


Figure E-36. GROUP CCE,SEPTEMBER-OCTOBER 1992, 3-M Distance, Modified Muff.

a. CCE-3 was a conditional auditory failure after condition 4/6 with a TTS of 17 dB at 8 kHz after the 20 minute test.

b. CCE-3 was a conditonal auditory failure after condition 4/12 with a TTS of 16 dB at 8 kHz at the 1 hour test.

c. CCE-2 could not meet his baseline at 1 kHz in his right ear. He was given Actifed® and his exposure to condition 6/6 was delayed.

d. CCE-1 was an auditory failure after 6/6. He has a TTS of 28 dB at 6 kHz at the 20 minute test.

e. CCE-4 elected not to be exposed to level 7/6.

f. CCE-3 was a conditional auditory failure after 3/25 with a TTS at 8 kHz that grew to a level of 21 dB at 1 hr.

g. CCE-1 was an auditory failure after exposure to 5/50. He has a TTS of 28 dB at 3 kHz. Because of problems at home (sick grandmother) he elected to stop further exposures at this time.

h. CCE-2, CCE-4, CCE-5 elected not to be exposed to condition 6/100 because of their concerns of the difficulty in enduring such an exposure.

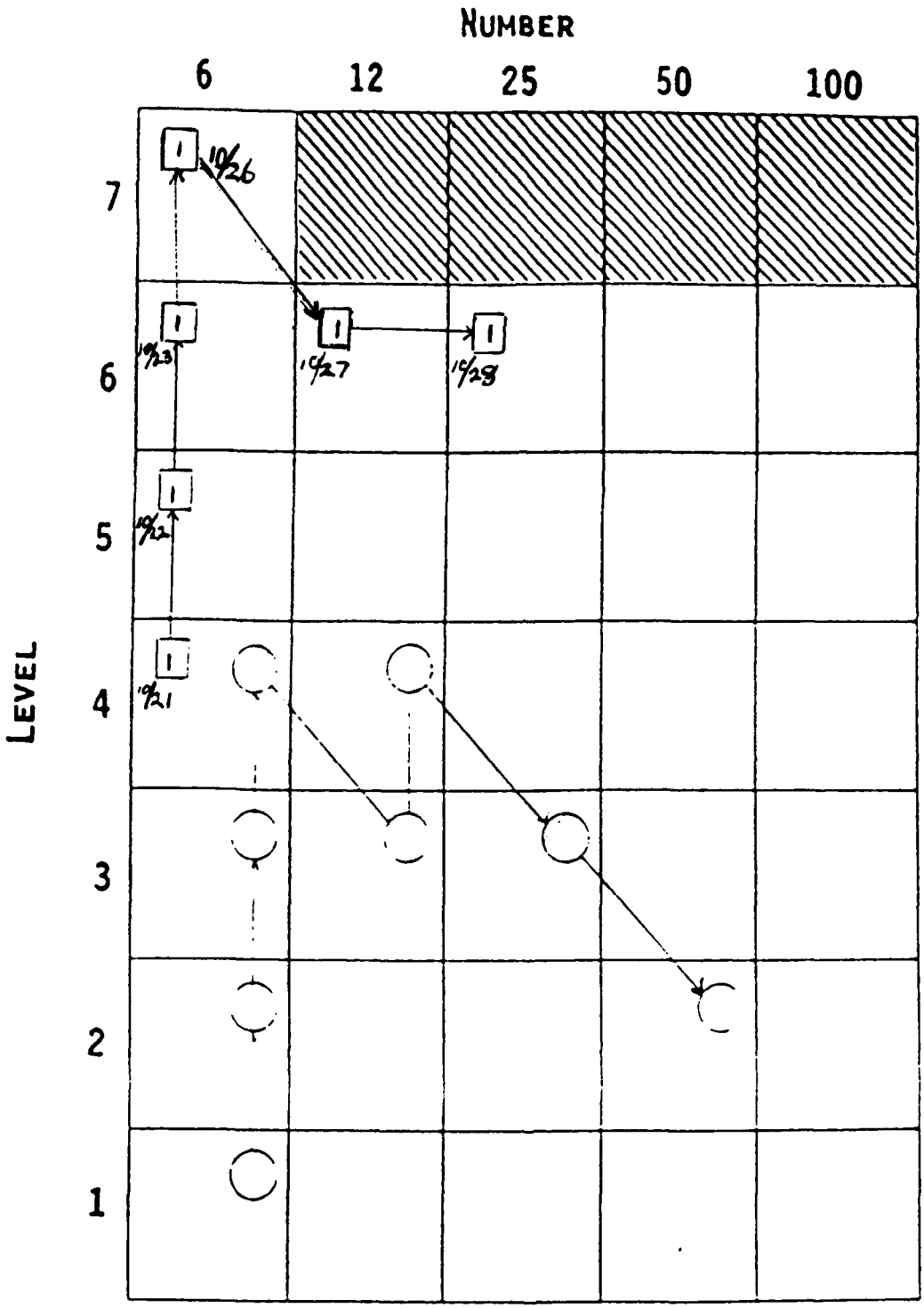


Figure E-37. SUBJECT CCE-3,OCTOBER 1992, 3-M Distance, Modified Muff.

a. CCE-3 second-level hearing protection.

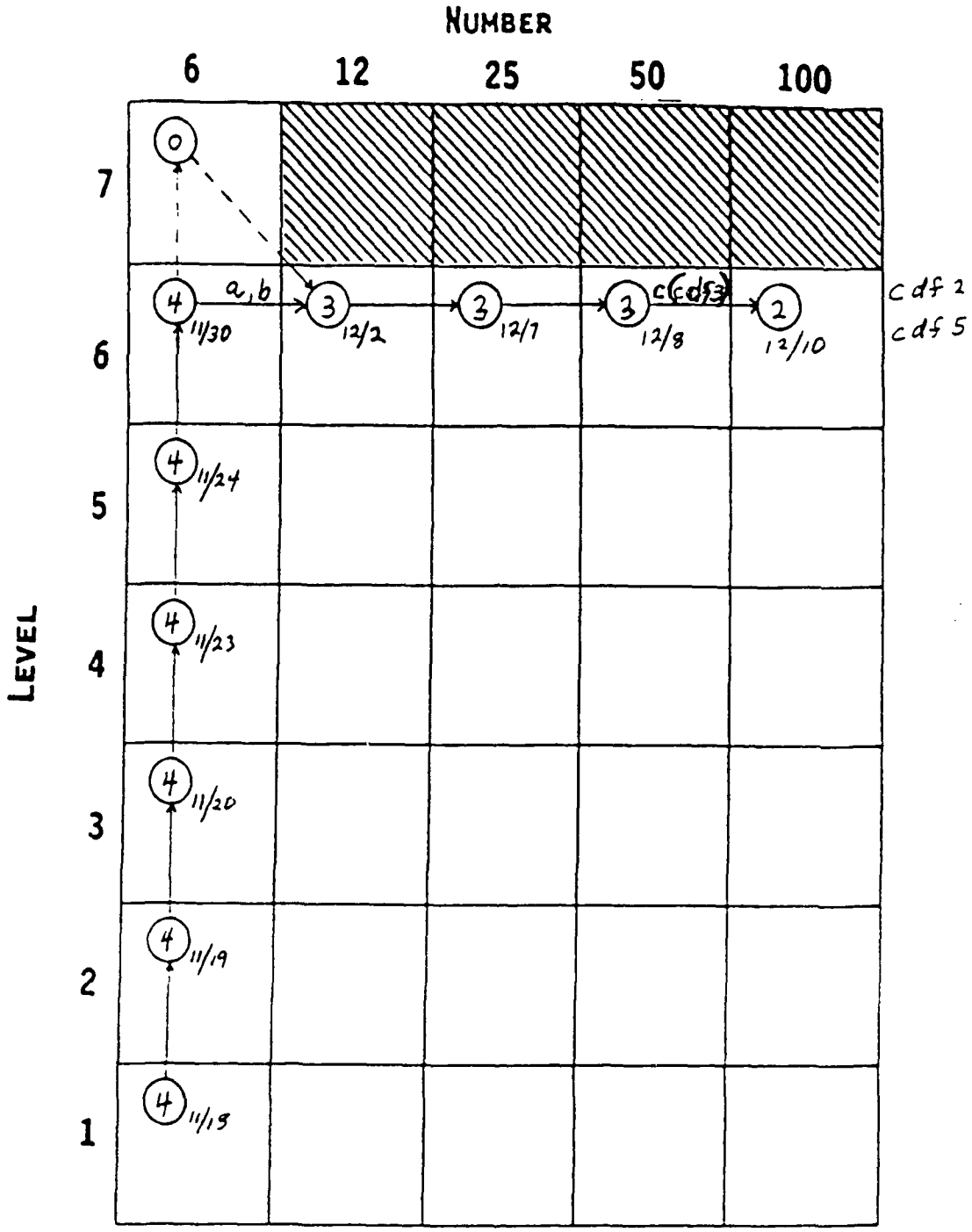


Figure E-38. GROUP CDF, NOVEMBER-DECEMBER 1992,3-M Distance,Modified Muff.

a. CDF-4 was drooped from the study after level 6/6 because of anemia.
b. CDF-2, CDF-3 and CDF-5 elected not to be exposed to level 7.
c. CDF-3 elected not to be exposed to level 6/100.

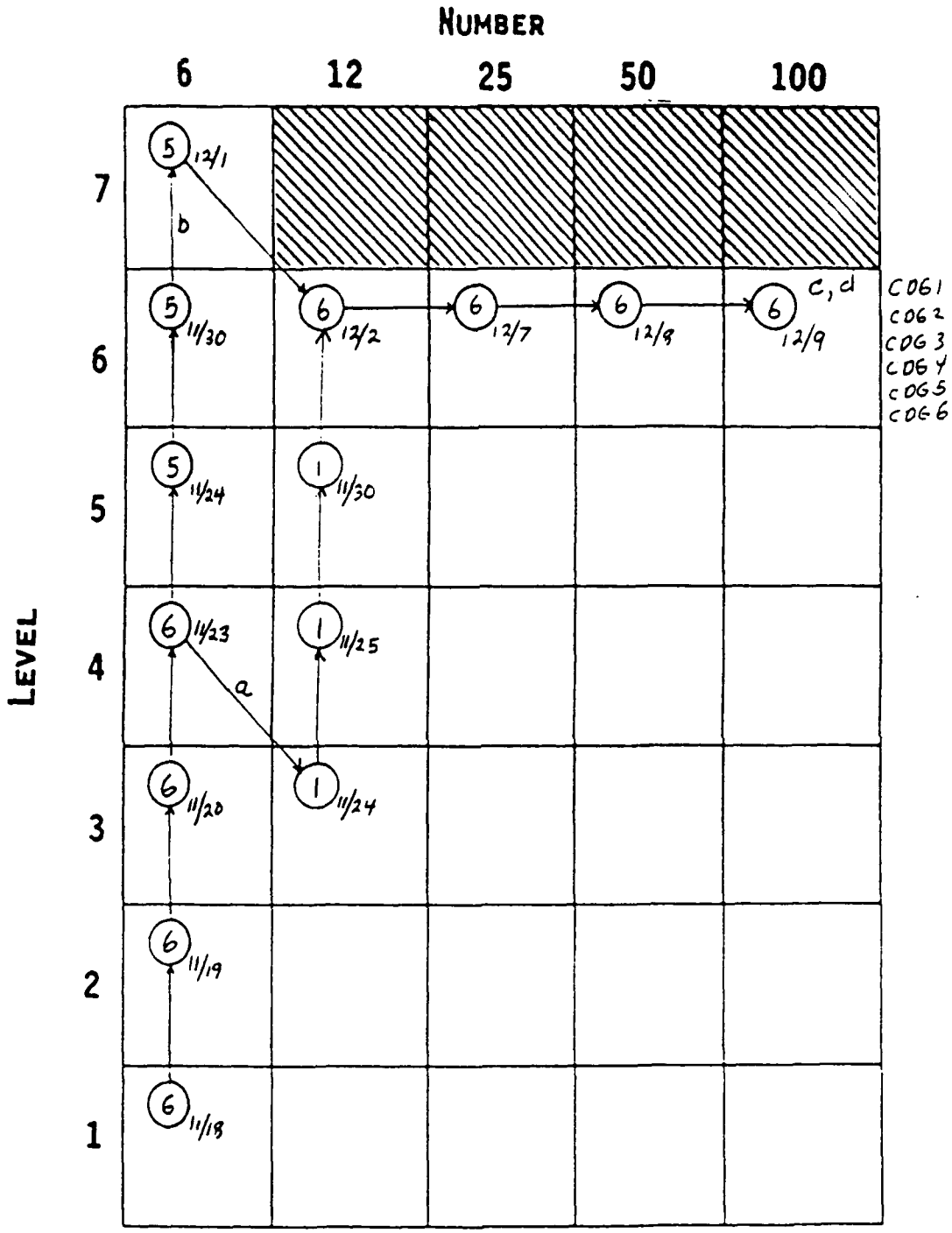


Figure E-39. GROUP CDG,NOVEMBER-DECEMBER 1992,3-M Distance,Modified Muff.

a. CDG-3 was a conditional failure after 4/6 with a TTS of 23 dB at 8 kHz.
b. CDG-2 elected to leave the pad after one exposure at level 7/6.
c. CDG-2 elected to stop exposures after 59 shots during level 6/100.
d. CDG-3 elected not to go to level 7 after exposure to level 6/100.

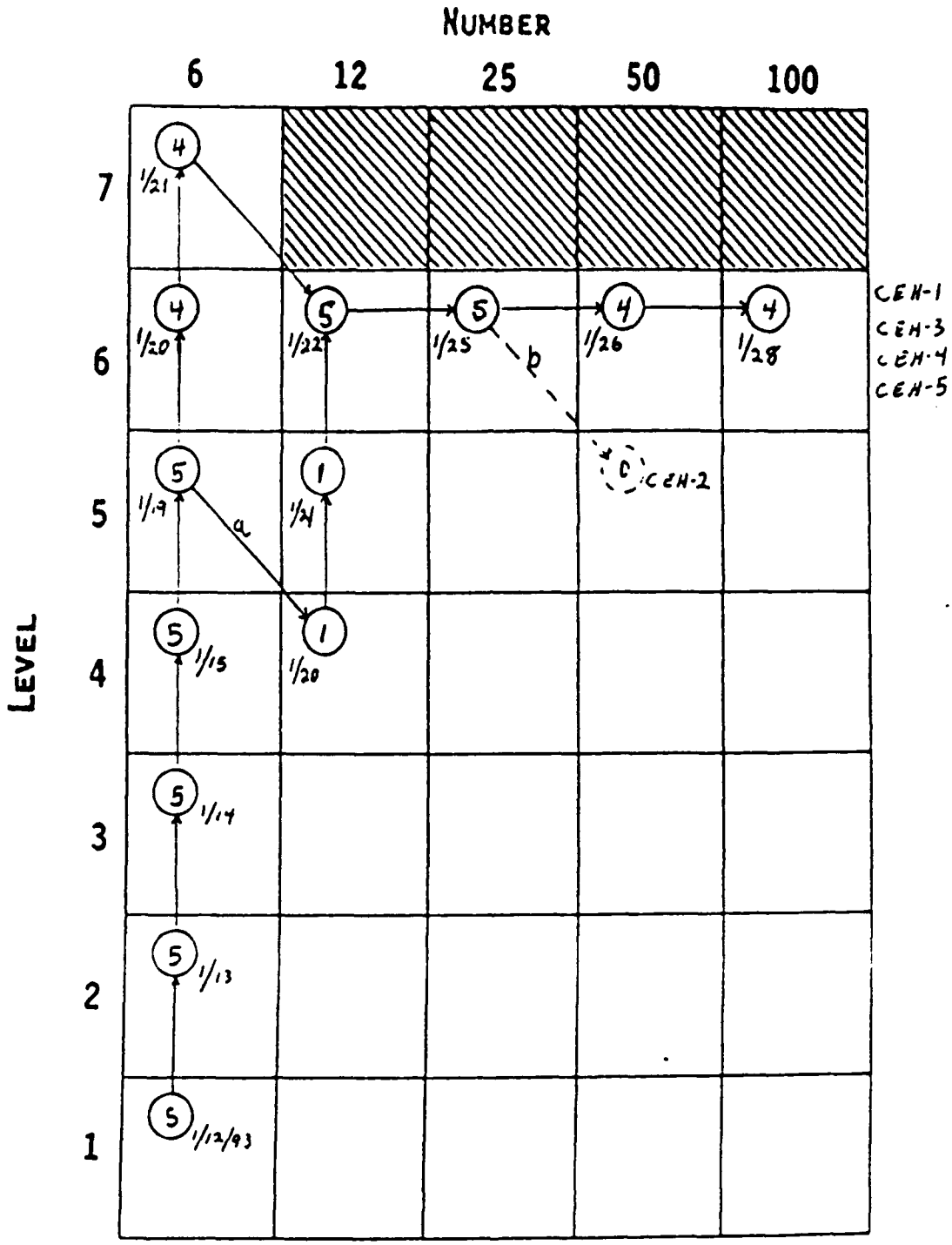


Figure E-40. GROUP CEH, JANUARY-FEBRUARY 1993, 3-M Distance, Modified Muff.

a. CEH-2 was considered a conditional auditory failure after condition 5/6 with a elevated threshold across all frequencies.

b. CEH-2 elected to leave the pad after the 9th shot of condition 6/25. He has a TTS of 13 dB at 500 Hz and 2000 Hz, 18-minutes post expose. He was considered a probable conditional auditory failure. This subject elected to stop further exposures.

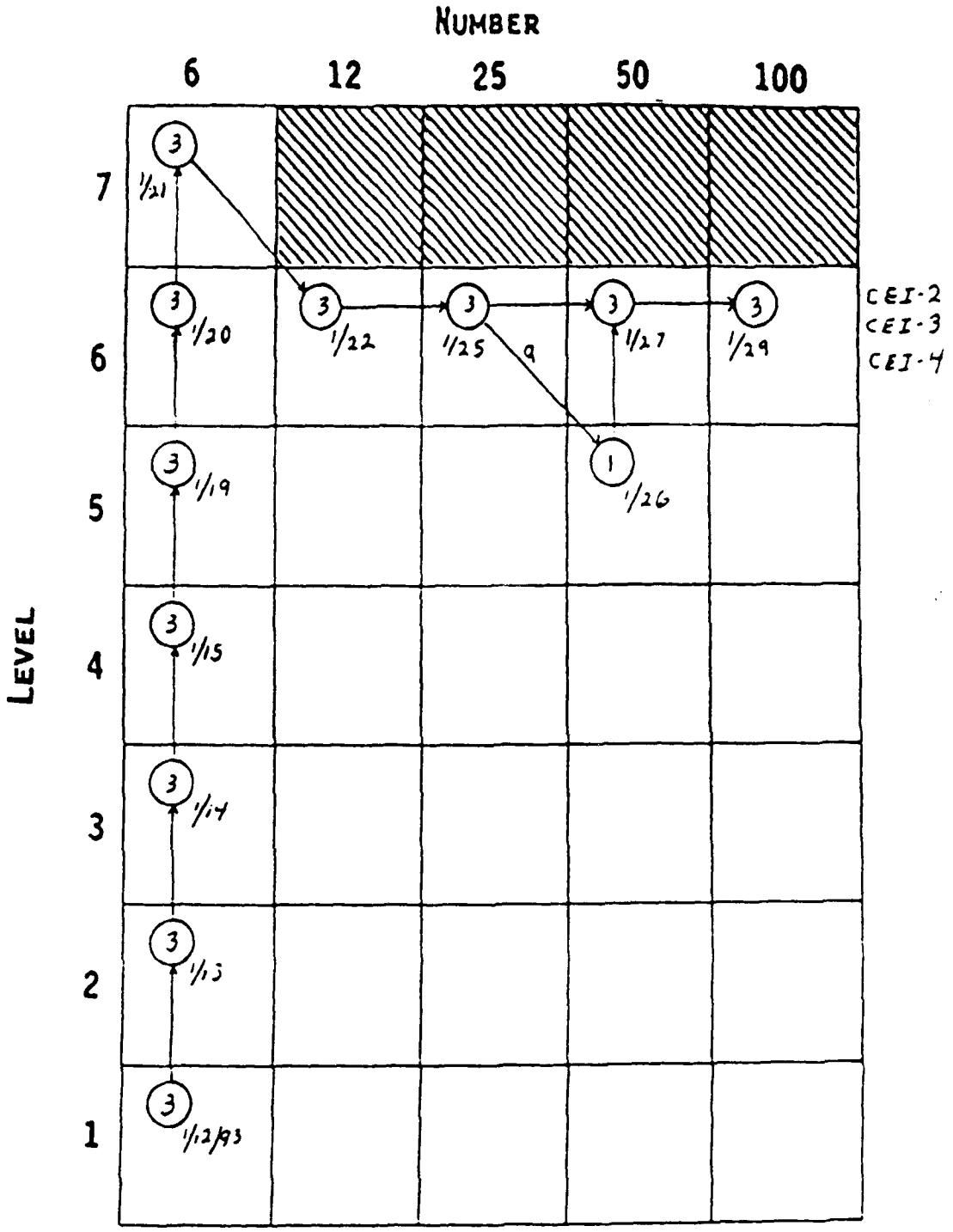


Figure E-41. GROUP CEI, JANUARY-FEBRUARY 1993, 3-M Distance, Modified Muff.

a. CEI-4 has a TTS of 16 dB at 8 kHz after condition 6/25.

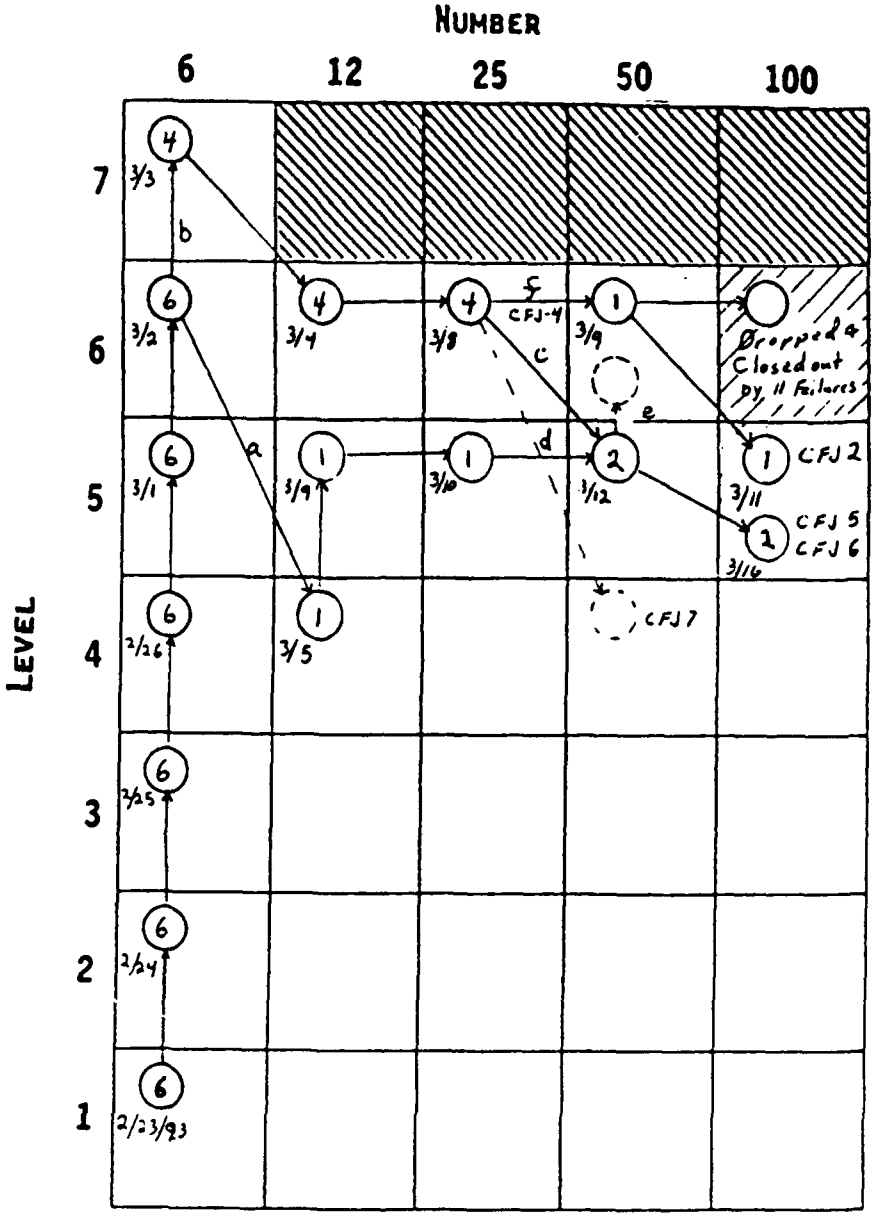


Figure E-42. GROUP CFJ, FEBRUARY-MARCH 1993, 3-M Distance, Modified Muff.

a. CFJ-5 was an auditory failure with a TTS at 8 kHz of 49 dB.

b. CFJ-3 was administratively dropped because he was arrested for using controlled substances.

c. CFJ-6 was a conditional auditory failure after 6/25 with a TTS of 17 dB at 2 kHz.

d. CFJ-7 was a failure after condition 6/25 with a TTS at 2 minutes of 25 dB at 4 kHz. This TTS grew to 43 dB at 1 hr. before recovery started. While recovery was complete within 24 hours, the subject was dropped from further exposure due to the TTS growth pattern.

e. CFJ-6 elected not to go to 6/50 after passing 5/50. He did go to condition 5/100.

f. CFJ-4 complained of a sore throat after 6/25. Dr. Neal of Lovelace recommended that he not be exposed again until his throat cleared. The subject said he would blast again only if his throat would not be bothered. The PI considers him an elective failure.

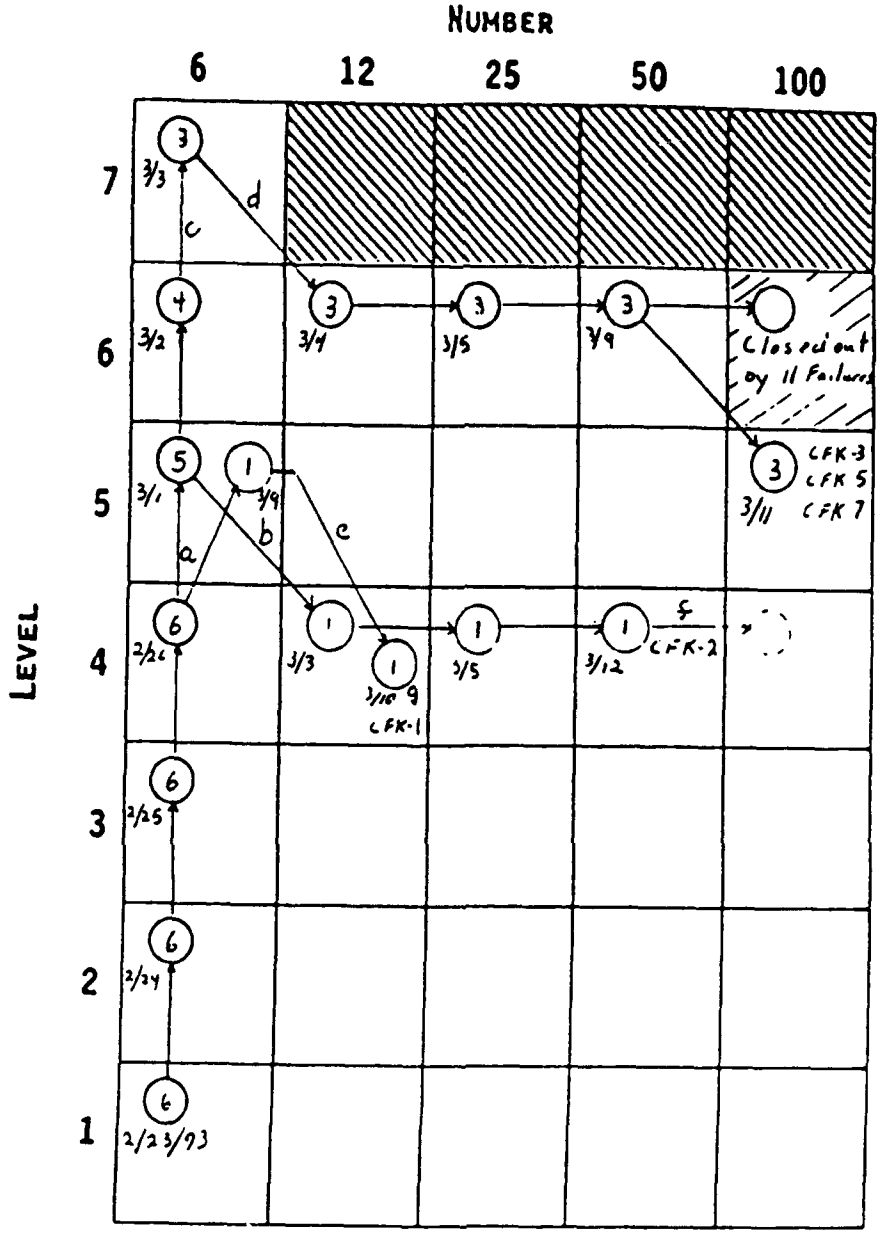


Figure E-43. GROUP CFK, FEBRUARY-MARCH 1993, 3-M Distance, Modified Muff.

a. CFK-1 could not meet his baseline at 3 Khz and 8 kHz. Met his baseline on 3/9 and was exposed at that time.

b. CFK-2 was an auditory failure with a TTS at 4 Khz of 21 dB at 2 min. and 27 dB at 20 min.

c. CFK-6 was administratively dropped for being arrested for using controlled substances.

d. CFK-3 was a conditional auditory failure with a TTS of 18 dB at 8 kHz.

e. CFK-1 was a conditional auditory failure after 5/6 with a TTS of 17 dB at 3 kHz.

f. CFK-2 elected not to be exposed to condition 5/100.

g. CFK-1 could not consistently meet his baseline after condition 4/12. He would meet it sometimes and not others. He was dropped on 3/15/93.

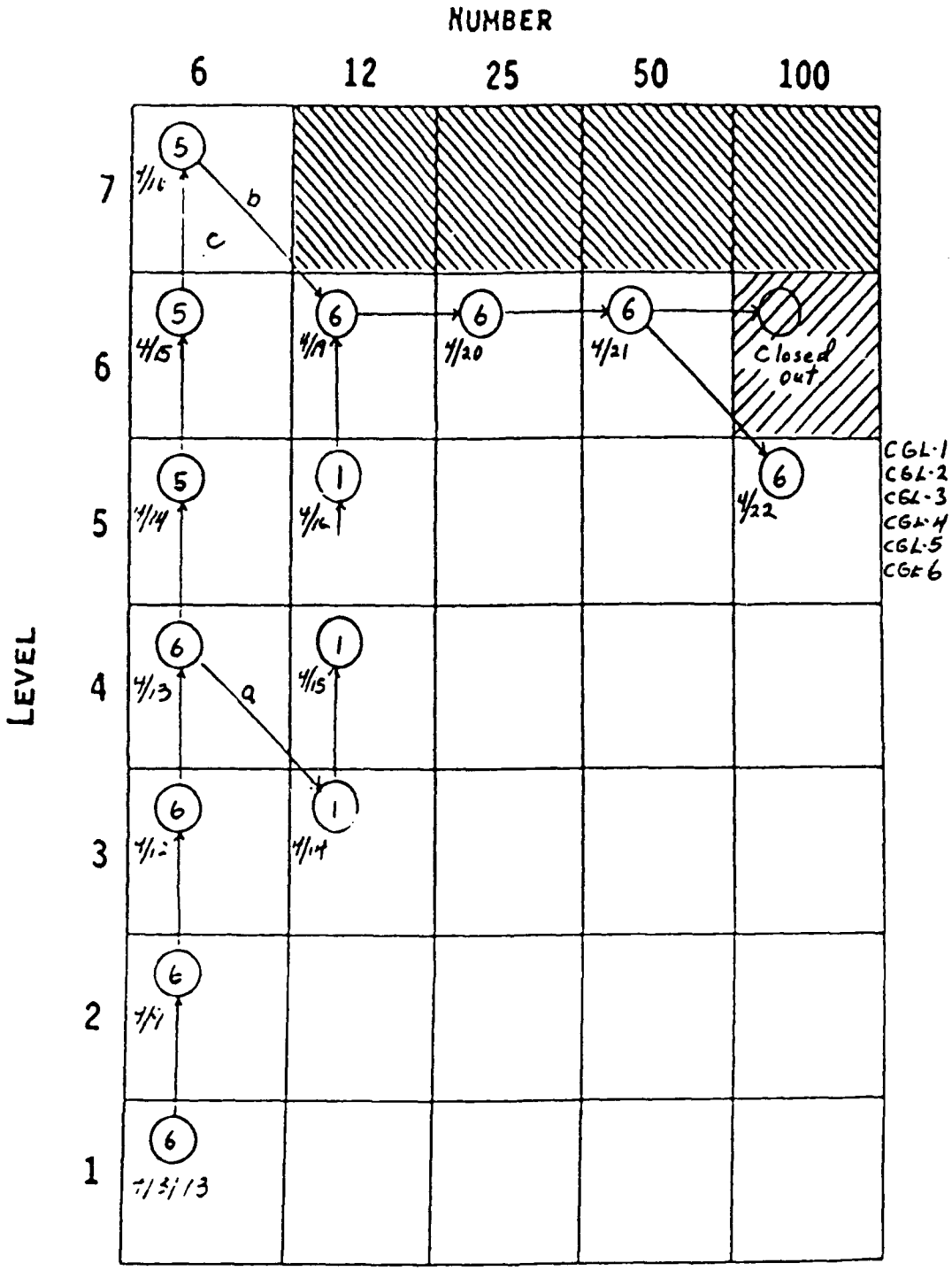


Figure E-44. GROUP CGL, MARCH-APRIL 1993, 3-M Distance, Modified Muff.

a. CGL-4 was a conditional auditory failure after condition 4/6 with a TTS of 22 dB at 4 kHz and 20 dB at 3 kHz.

b. CGL-3 was a conditional auditory failure after condition 7/6 with a TTS of 21 dB at 8 kHz.

c. CGL-4 elected not to be exposed to condition 7/6.

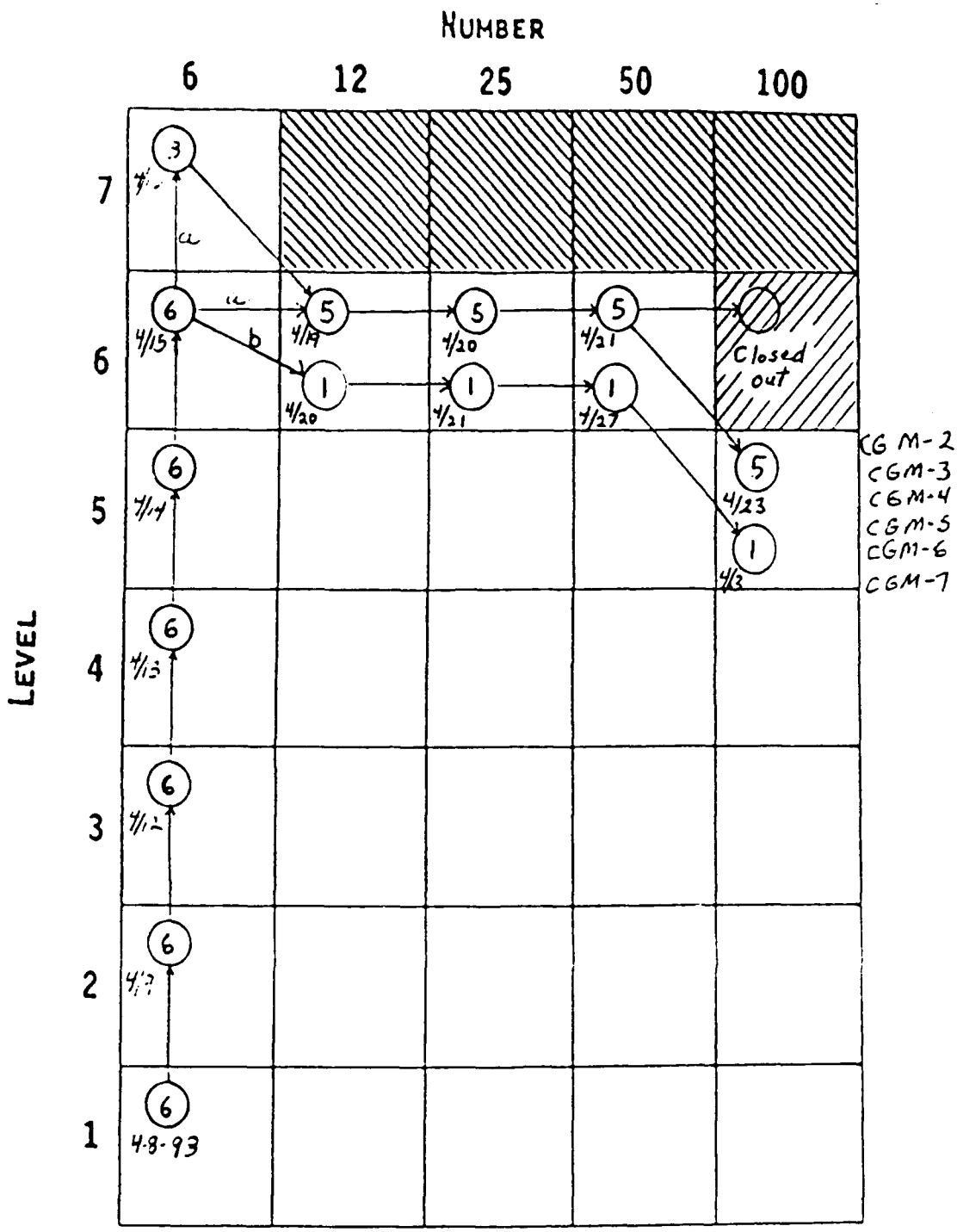


Figure E-45. GROUP CGM, MARCH-APRIL 1993, 3-M Distance, Modified Muff.

a. CGM-1, CGM-2, AND CGM-5 elected not to be exposed to condition 7/6. The all continued with condition 6/12.

b. CGM-1 was elevated at 4 kHz at his right ear during his pre-blast audiogram. This was likely due to his cold and general mild middle ear infection. He was not exposed on April 19.

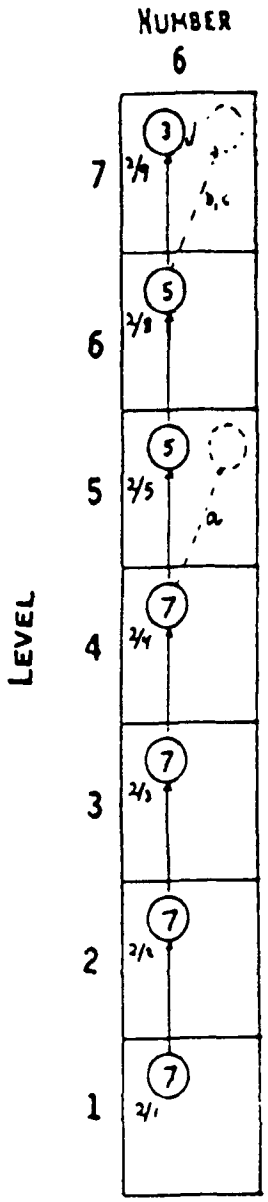


Figure E-46. NO COUNTDOWN GROUPS CEH-CEI, FEBRUARY 1993, 3-M Distance, Modified Muff.

a. CEH-4 and CEH-5 stopped after condition 4/6 because both had ringing in their right ears immediately after the exposure. The ringing quickly disappeared and there was no signs of TTS in these subjects.

b. CEI-2 elected to stop after exposure to condition 6/6 because of a TTS of 15 dB at 8 kHz.

c. CEI-3 elected to stop after condition 6/6 because of intermittent ringing and headaches due to exposure to conditions 5/6 and 6/6.

d. CEI-4 elected to stop after the second shot at condition 7/6. He reported as the reason that the exposures were just "too much."

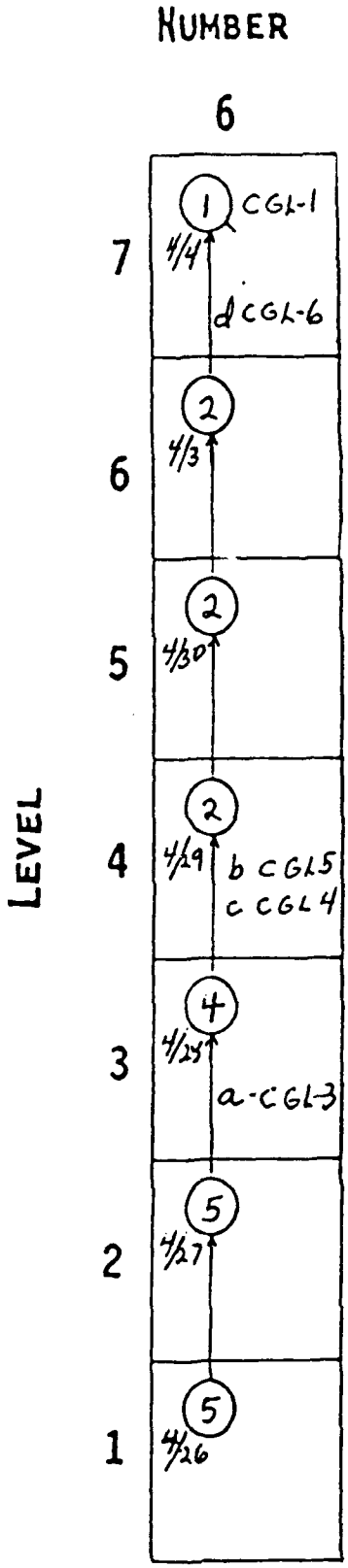


Figure E-47. NO COUNTDOWN GROUP CGL, APRIL 1993, 3-M Distance, Modified Muff.

a. CGL-3 elected to stop after level 2. He stated he was too tense waiting for the shot to go off

b. CGL-5 was a conditional auditory failure after level 3 with a TTS of 16 dB at 3 kHz

c. CGL-5 could not meet his baseline at 6 kHz prior to level 4. Became an elective failure when he declined to continue the next day.

d. CGL-6 complained that one of the shots especially bothered him after level 6. Was an elective failure for level 7.

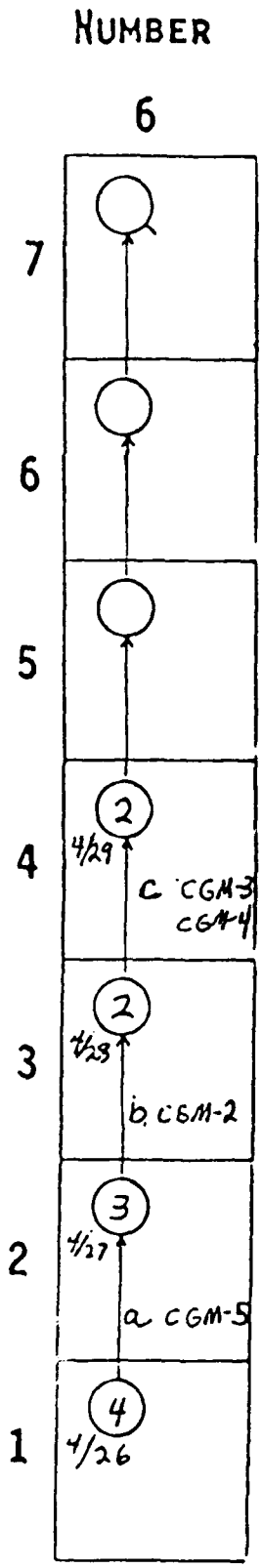


Figure E-48. NO COUNTDOWN GROUP CGM, APRIL 1993, 3-M Distance, Modified Muff.

a. CGM-5 became ill before level 2. Was elevated at several frequencies and did not feel like being exposed. Was also sick the next day and elected to quit at that time.

b. CGM-2 elected to stop after level 2. He claimed his ringing was louder with the no-countdown exposure.

c. CGM-3 and CGM-4 were elective failures at level 4. CGM-3 stated that the lack of countdown made the exposure harder to bear and he already observed that the step between level 4 and level 5 was greater. CGM-4 stated he was tired of the study including doing audiogram.

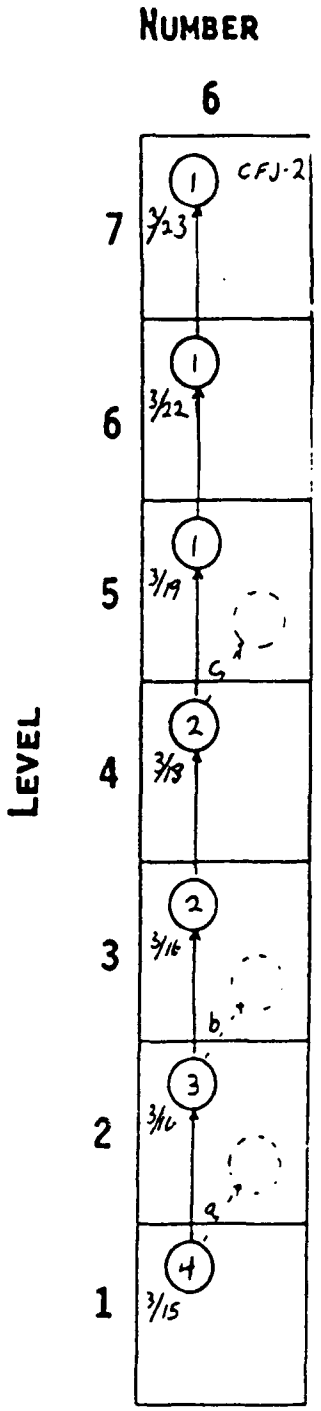


Figure E-49. NO COUNTDOWN GROUP CFK, MARCH 1993, 3-M Distance, Modified Muff.

a. CFK-7 elected to quit after 1/6.
b. CFK-3 elected to quit after 2/6.
c. CFK-5 elected to quit after 4/6.

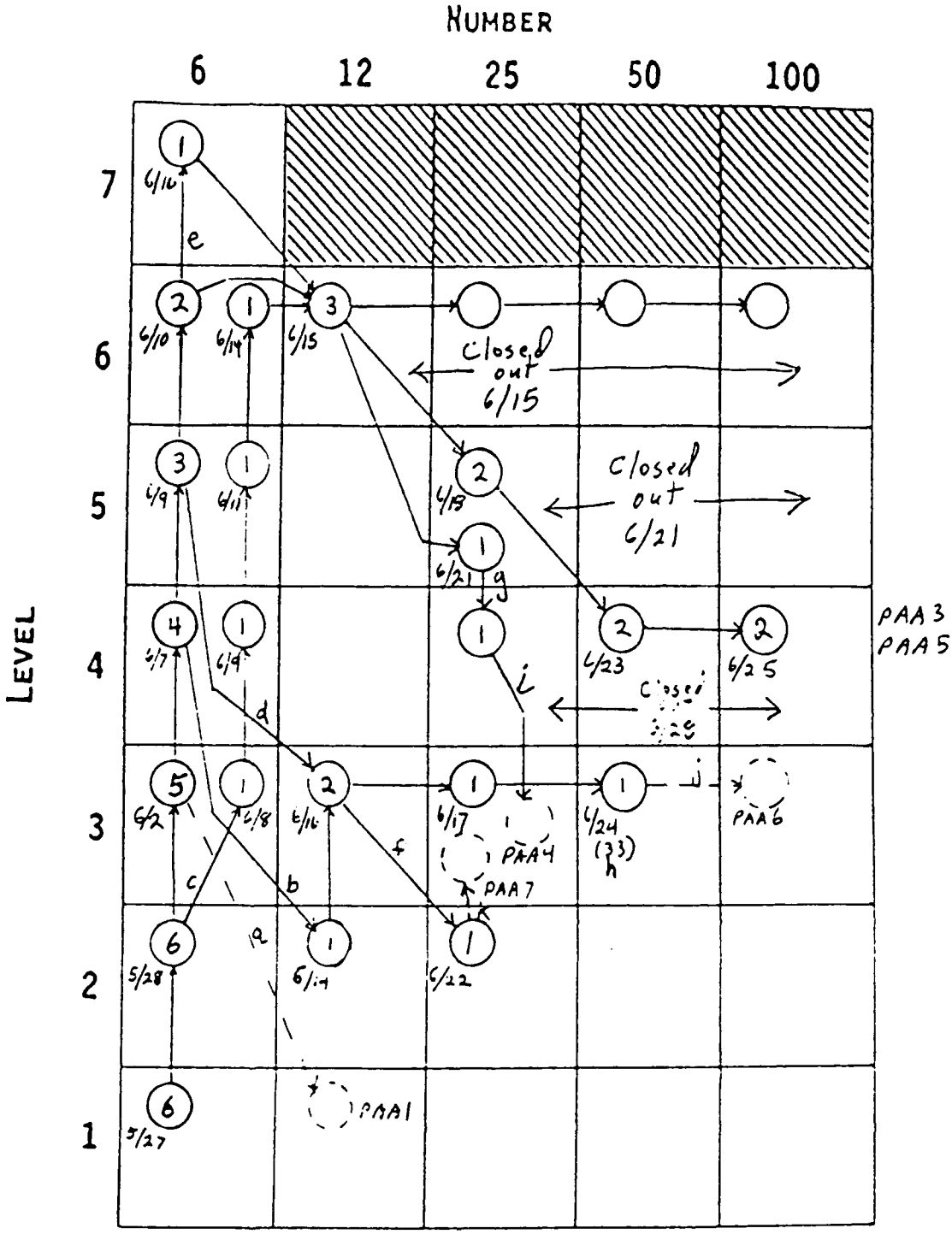


Figure E-50. GROUP PAA, MAY-JUNE 1993, 3-M Distance, Perforated Ear Plugs.

Figure E-50. GROUP PAA, MAY-JUNE 1993, 3-M Distance, Perforated Ear Plugs.

a. PAA-1 was an auditory failure with a TTS of 32 dB at 6 Khz. This TTS was 13 dB at 24 hr, fully recovered to 0 db in 48 hrs. This subject was dropped from further exposure because of the slow recovery.

b. PAA-6 was an auditory failure with a TTS of 40 dB at 8 kHz. He recovered by 2. hr. This subject had a hematoma in his left ear canal possibly due to E.A.R. foam plug movement.

c. PAA-3 broke a toe playing soccer and was delayed for several days.

d. PAA-7 was an auditory failure after 5/6 whit TTS at 3 kHz of 27 dB.

e. PAA-4 and PAA-5 elected no to go to level 7. Subject PAA-3 passed level 7 on 16 June.

f. PAA-7 was a conditional auditory failure whit at TTS of 20 dB at 2 kHz.

g. PAA-4 was an auditory failure with a TTS of 30 dB at 4 kHz after condition 5/25.

h. PAA-6 stopped after 33 shots at level 3 because of ear pain and ringing. While he stopped exactly at 33 shots because of subject PAB-4, he stated positively he would not have taken 50 shots.

i. PAA-4 was an auditory failure with a TTS of 46 dB at 2 kHz after condition 4/25. Because of increasing sensitivity with decreasing level, the PI elected no to further expose the subject. In any case, the subject also elected to stop the exposures.

j. PAA-6 elected to stop further exposures because of concern for his hearing. He also experienced some occasional ringing.

k. PAA-7 elected to stop further exposures because of concerns for his hearing and the fact that he had some ringing.

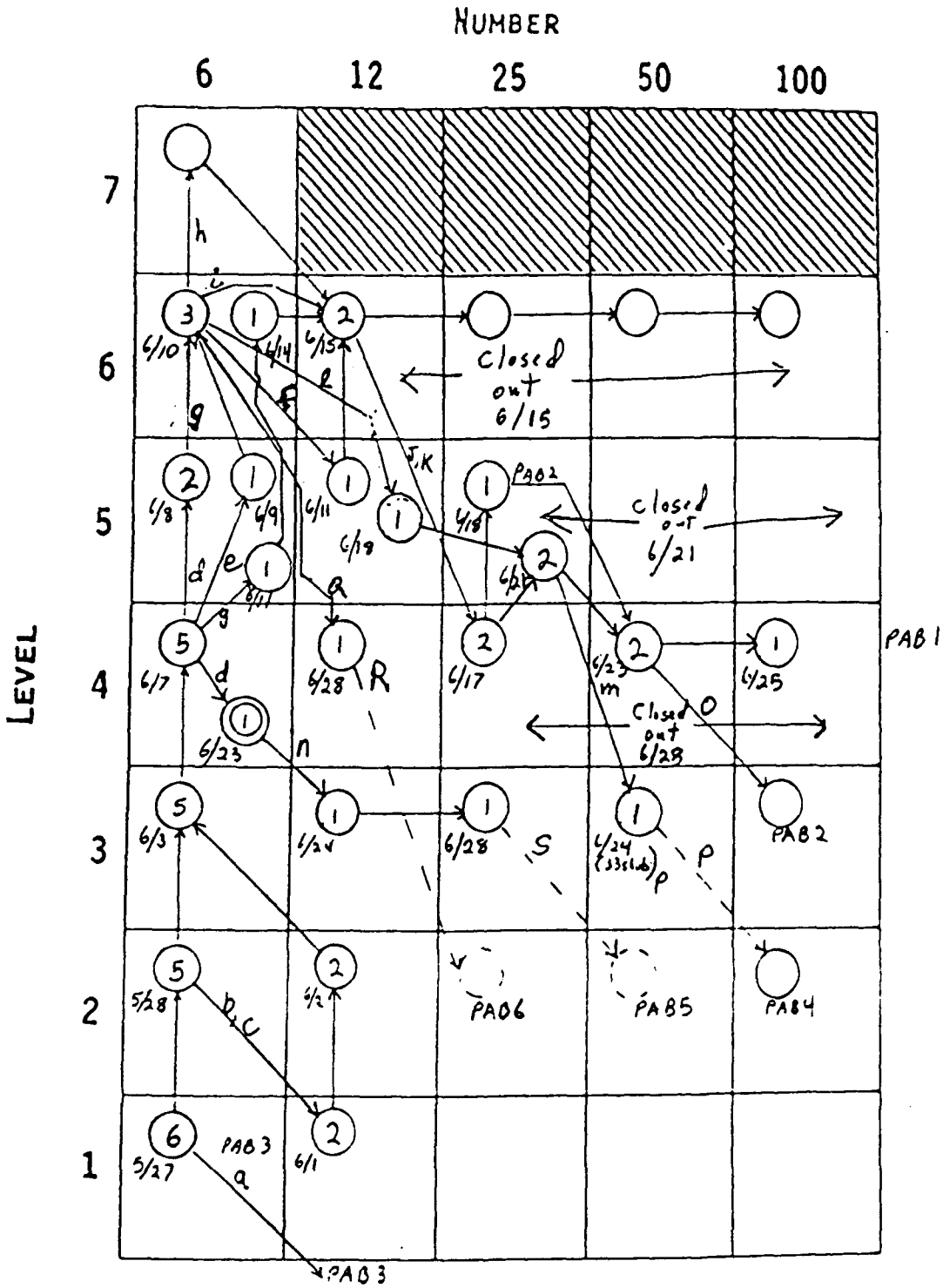


Figure E-51. GROUP PAB, MAY-JUNE 1993, 3-M Distance, Perforated Ear Plugs.

Figure E-51. GROUP PAB, MAY-JUNE 1993, 3-M Distance, Perforated Ear Plugs.

a. PAB-3 was a conditional auditory failure after 1/6. He was then started on second level hearing protection. The failure was a TTS of 20 dB at 4 kHz.

b. PAB-4 was a conditional auditory failure after 2/6. The failure was 17 dB of TTS at 4 kHz.

c. PAB-6 was a conditional auditory failure after 2/6. The failure was a TTS of 17 dB at 500 Hz.

d. PAA-5 had a hematoma on his right tympanic membrane after condition 4/6. Further exposure was delayed until recovery. This recovery occurred 17 June, 1993. (see note "n" below)

e. PAB-1 could not meet his baseline attenuation curves for the perforated plug. He showed 5-8 dB less than normal attenuation in spite of two complete refits and numerous re-tests. His unoccluded tests were normal. He was exposed the following day and rejoined his group for level 6/6.

f. PAB-2 was a conditional auditory failure after 6/6 with a 17 dB TTS at 8 kHz.

g. PAB-4 was dropped, the reinstated, after condition 4/6 because of disciplinary problems.

h. PAB-1, PAB-4, and PAB-6 elected not to go to level 7.

i. PAB-1 and PAB-6 were sick prior to condition 6/12 and were not exposed on 6/15/93.

j. PAB-2 was an auditory failure after 6/12 with a TTS of 33 dB at 4 kHz.

k. PAB-4 was an auditory failure with a TTS of 50 dB at 4 kHz.

l. PAB-1 was sick on 15 and 16 June. The PI decided to expose him at 5/12 instead of 6/12 on 18 June.

m. PAB-4 was an auditory failure with a TTS of 32 dB at 4 kHz after condition 5/25.

n. PAB-5 was exposed to 1 shot at level 4. No problem occurred. He was then exposed to condition 3/12.

o. PAB-2 was a conditional auditory failure after condition 4/50 with a TTS of 18 dB at 3 kHz. Because of some ringing, he elected to stop at this point.

p. PAB-4 stopped after 33 shots because of ringing that subjectively matched the ringing when he had 30 dB TTS. He was a conditional auditory failure after 3/33 with a TTS of 20 dB at 4 kHz. He elected to stop further exposures at this point.

q. PAB-6 was sick on 15 June and told by Kirtland AFB physician that he could not be exposed for a week. When he recovered, condition 6/12 was closed and he elected to go to 4/12.

r. PAB-6 was auditory failure with at TTS of 17 dB at 2 kHz at 2 min. This TTS grew to reach a maximum of 31 dB at 7 hr, at which time recovery started. This subject was dropped from further exposures.

s. PAB-5 was a conditional auditory failure with a TTS of 17 dB at 2 kHz at 20 Min. after condition 3/25 He elected to stop further exposure at this time.

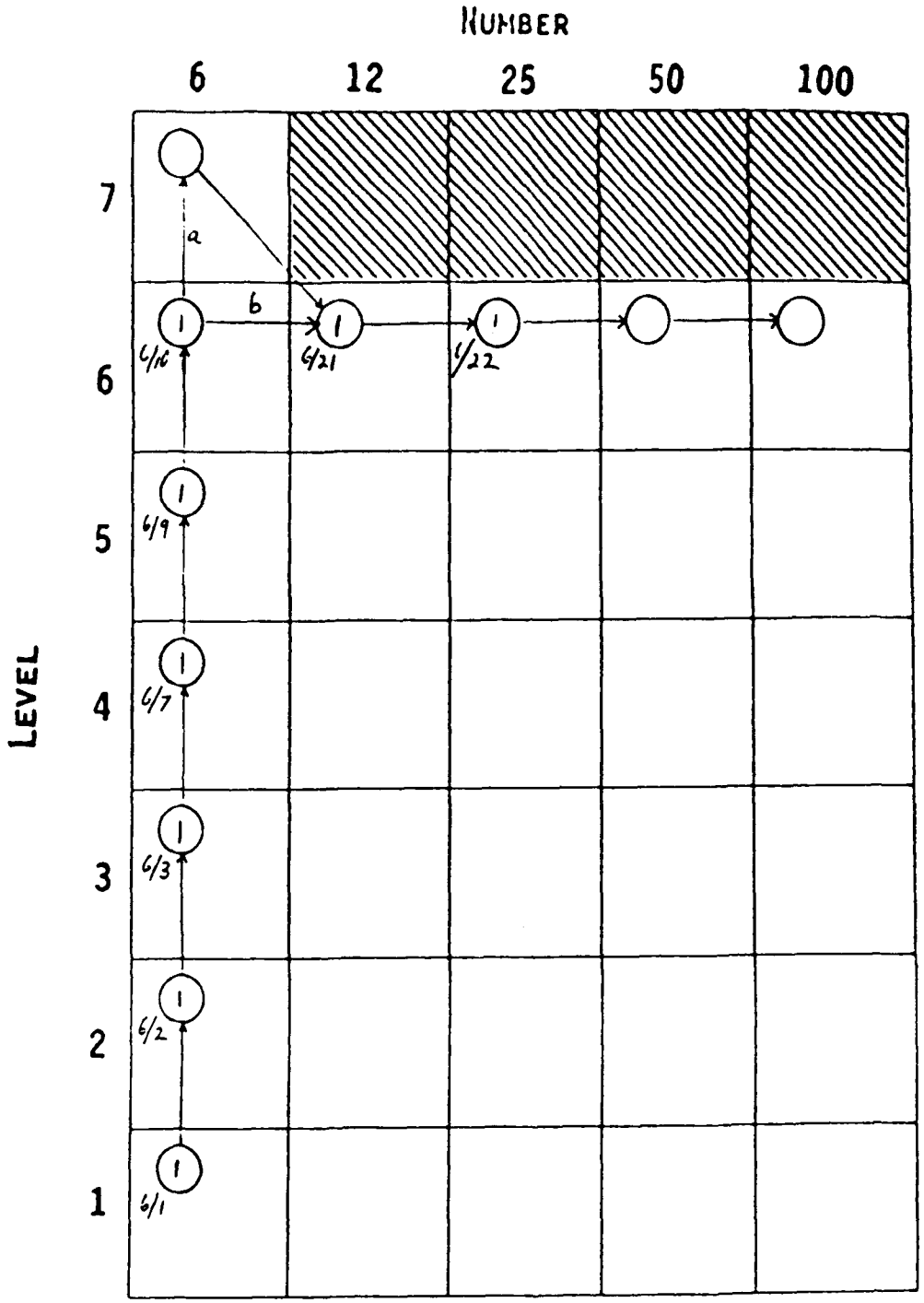


Figure E-52. SUBJECT PAB-3, SECOND LEVEL HEARING PROTECTION, MAY-JUNE 1993, 3-M Distance, Perforated Ear Plugs.

a. PAB-3 elected no to be exposed to level 7.
b. PAB-3 was sick for over a week.

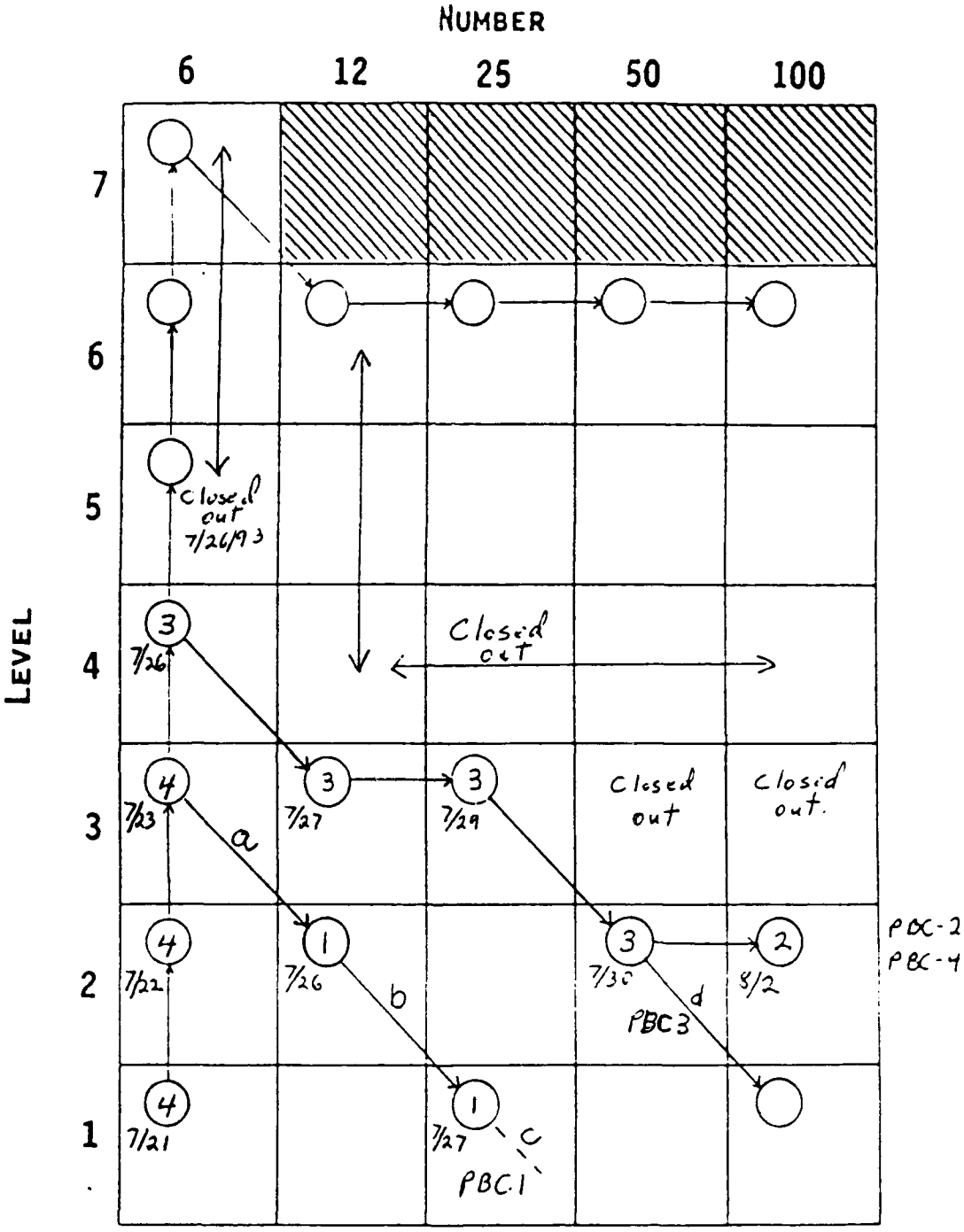


Figure E-53. GROUP PBC, FIRST-LEVEL HEARING PROTECTION, JULY-AUGUST 1993, 3-M Distance, Perforated Ear Plugs.

a. PBC-1 was a conditional auditory failure after 3/6. He had a TTS of 20 dB at 8 kHz.

b. PBC-1 was a conditional auditory failure after 2/12. He had a TTS of 20 dB at 8 kHz.

c. PBC-1 was an auditory failure after 1/25. He had a TTS of 27 dB at 8 kHz. His exposures with first-level hearing protection were stopped.

d. PBC-3 was a conditional auditory failure after 2/50 with at TTS of 21 dB at 500 Hz. He then elected not to be exposed to condition 1/100.

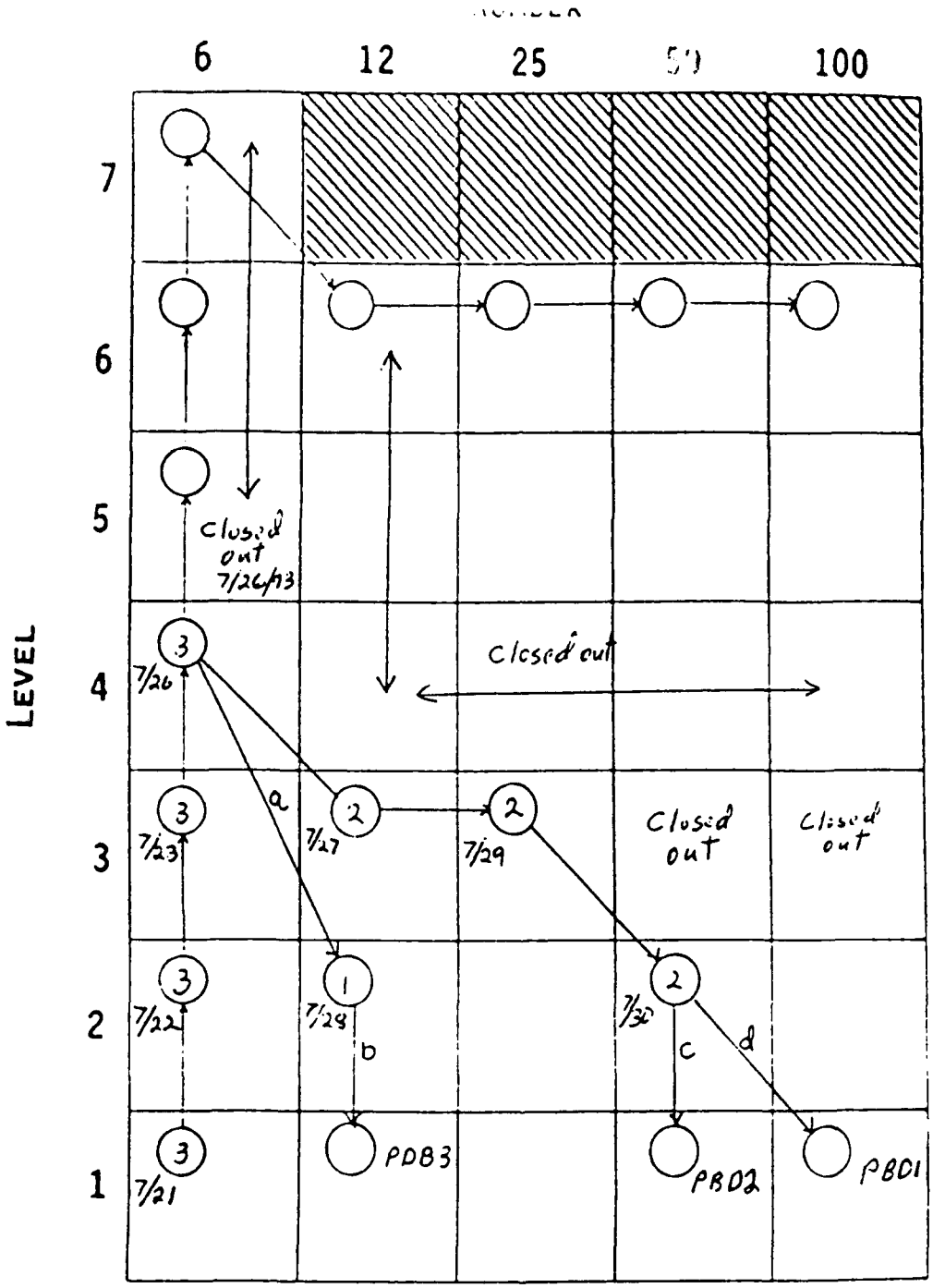


Figure E-54. GROUP PBD, FIRST-LEVEL HEARING PROTECTION, JULY-AUGUST 1993, 3-M Distance, Perforated Ear Plugs.

a. PBD-3 was an auditory failure after condition 4/6. He has a TTS of 28 dB at 2 kHz at 2 min. and a TTS of 21 dB at 3 kHz at 20 min.

b. PBD-3 was an auditory failure after condition 2/12 with a TTS of 31 dB at 2 kHz. He also had a TTS of 17 dB at 3 kHz. This TTS did not recover within 24 hr, so the subject was dropped from further exposure.

c. PBD-2 was an auditory failure after condition 2/50. He had a TTS of 25 dB at 4 kHz. He elected not to be exposed to condition 1/50.

d. PBD-1 was an elective failure for condition 2/100. He was willing, however, to be exposed to condition 1/100. He then changed his mind on 3 August and became an elective failure for 1/100 also.

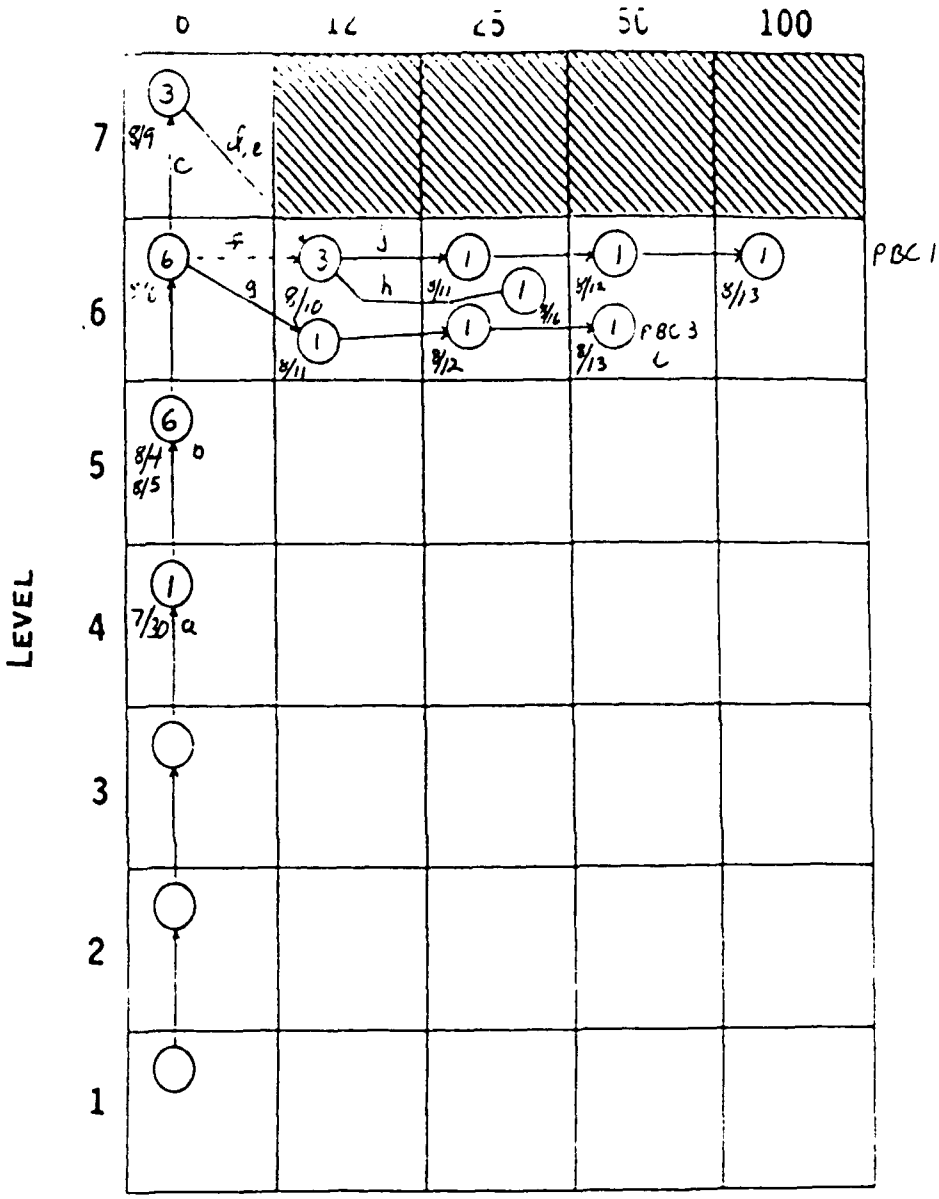


Figure E-55. GROUP PBC-PBD, SECOND-LEVEL HEARING PROTECTION, JULY-AUGUST 1993, 3-M Distance, Perforated Ear Plugs.

a. PBC-1 started second-level hearing protection at condition 4/6.
b. PBC-2, PBC-3, PBD-1, and PBD-2 all started second-level hearing protection whit condition 5/6 on 4 August 1993.
c. PBC-2, PBC-3, and PBD-1 all elected not to be exposed to condition 7/6.
d. PBC-4 was a conditional auditory failure after 7/6 with a TTS of 21 dB at 8 kHz and a TTS of 18 dB at 2 kHz.
e. PBD-2 was an elective failure for condition 6/12. Although he passed both conditions 6/6 and 7/6, he felt that level 6 was bothersome and painful.
f. PBD-1 was an elective failure for 7/6, went to condition 6/12. PBC-2, also an elective failure for 7/6, was an elective failure for 6/12.
g. PBC-3 first elected to stop before condition 6/12, then changed his mind. He was exposed to condition 6/12 a day later that the rest of the subjects.
h. PBC-4 was delayed several days because of a sinus infection. He was willing to be exposed to condition 6/25 on 16 August, but should be considered and elective failure for condition 6/50.
i. PBC-3 was willing to go to condition 6/50 only if he could stop after that exposure. He should be considered an elective failure for condition 6/100.
j. PBD-1 elected to stop further exposures after condition 6/12.