ANSI/ASA S12.6-2008
(Revision of ANSI S12.6-1997)

AMERICAN NATIONAL STANDARD

Methods for Measuring the Real-Ear Attenuation of Hearing Protectors

ANSI/ASA S12.6-2008

Accredited Standards Committee S12, Noise

Standards Secretariat
Acoustical Society of America
35 Pinelawn Road, Suite 114 E
Melville, NY 11747-3177

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Methods for Measuring the Real-Ear Attenuation of Hearing Protectors

Secretariat
Acoustical Society of America

Approved September 3, 2008
American National Standards Institute, Inc.

Abstract

This Standard specifies laboratory-based procedures for measuring, analyzing, and reporting the passive noise-reducing capabilities of hearing protection devices. The procedures consist of psychophysical tests conducted on human subjects to determine the real-ear attenuation measured at hearing threshold. Two fitting procedures are provided: Method A) trained-subject fit, intended to describe the capabilities of the devices fitted by thoroughly trained users, and Method B) inexperienced-subject fit, intended to approximate the protection that can be attained by groups of informed users in workplace hearing conservation programs. Regardless of test method, the attenuation data will be valid only to the extent that the users wear the devices in the same manner as during the tests. This Standard does not address issues pertaining to computational schemes or rating systems for applying hearing protector attenuation values (see ANSI/ASA S12.68), nor does it specify minimum performance values for hearing protectors, or address comfort or wearability features. Method A of this Standard corresponds to International Standard ISO 4869-1:1990, *Acoustics – Hearing protectors – Part 1: Subjective method for the measurement of sound attenuation*, and Method B corresponds to ISO/TS 4869-5:2006, *Acoustics – Hearing protectors – Part 5: Method for estimation of noise reduction using fitting by inexperienced test subjects*.

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Foreword

[*This Foreword is for information only and is not a part of the American National Standard ANSI/ASA S12.6-2008 American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors* (revision of ANSI S12.6-1997).]

This standard comprises a part of a group of definitions, standards, and specifications for use in noise. It was developed and approved by Accredited Standards Committee S12, Noise, under its approved operating procedures. Those procedures have been accredited by the American National Standards Institute (ANSI). The Scope of Accredited Standards Committee S12 is as follows:

> *Standards, specifications, and terminology in the field of acoustical noise pertaining to methods of measurement, evaluation, and control, including biological safety, tolerance, and comfort, and physical acoustics as related to environmental and occupational noise.*

This standard is a revision of ANSI S12.6-1997. The Method-A procedure has been modified to make it more specific and less open to interpretation, and has been re-designated as a "trained-subject fit." The Method-B procedure has also been clarified, and has been re-designated as "inexperienced-subject fit." The scope and applications have been revised accordingly.

This standard is comparable to two existing ISO Standards. Method A corresponds to ISO 4869-1:1990, *Acoustics – Hearing protectors – Part 1: Subjective method for the measurement of sound attenuation*, with the principal differences being in the number of test subjects and replications, the fitting instructions, and certain details of the electroacoustic test specifications, especially the room background noise. Method B corresponds to ISO/TS 4869-5:2006, *Acoustics – Hearing protectors – Part 5: Method for estimation of noise reduction using fitting by inexperienced test subjects*, again with similar differences as between Method A and 4869-1.

This standard does not include performance requirements for hearing protectors, nor does it specify how to utilize the attenuation values derived from testing via the methods of this standard for the prediction of protected noise exposures; computational methods and attenuation ratings are described in ANSI/ASA S12.68-2007. This standard also does not pertain to physical attenuation measurements using acoustical test fixtures or microphones mounted in human earcanals; those procedures are covered by ANSI S12.42-1995 (R2004).

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Introduction

Background

Since the development of ANSI Z24.22-1957, real-ear attenuation at threshold (REAT) methods for the measurement of the noise reduction of hearing protection devices (HPDs) have been widely utilized and described in the literature. In subsequent years, many additional procedures have been devised and tested, and in some cases standardized, but the real-ear attenuation procedure has remained the most commonly accepted (Berger, 1986). It is generally recognized that REAT data yield the best measure of the noise reduction provided by passive level-independent devices for a specified test condition and include effects of sound transmission from flanking pathways, such as those arising from tissue and bone conduction.

A major area of contention does exist in the professional community and within the scientific literature, namely, the applicability of the laboratory-measured REAT data to real-world environments. In other words, are the data valid for application outside the laboratory? Do they provide a useful indicator of the attenuation actually attained by individual well-trained users or by groups of people wearing hearing protectors on a day-to-day basis for protection from occupational or recreational noise exposures?

Beginning in the middle 1970s and continuing up through the 2000s, studies have reported that the field-measured attenuation of HPDs was substantially less than would be predicted based upon testing conducted in conformance with the prior ANSI standards, S3.19-1974 and S12.6-1984 (Berger, Franks, and Lindgren, 1996). This divergence is especially troubling considering the importance that many hearing protector purchasers and users ascribe to published attenuation data.

Ideally, the approach to reduction of laboratory vs. real-world discrepancies would be to ensure that end users properly fit and use hearing protectors in order to improve field performance to more closely match laboratory data, keeping in mind that rarely can one hope to duplicate optimum laboratory attenuation under field conditions. Regardless, most agree that industrial hearing conservation practices must be enhanced so that better real-world HPD performance can be realized (Berger, 1992). However, it is also clear that a laboratory method of measuring hearing protector attenuation that yields data that closely correlate with existing, or even potential, field performance would be a useful predictive tool.

The Working Group responsible for this standard embarked upon a project to develop a procedure to provide more valid estimates of field performance. Various protocols were evaluated and tested via both a pilot and a full-scale interlaboratory comparison study. The results, which have been summarized and presented in three parts, provide the scientific justification for the inexperienced-subject procedure that has been incorporated in this standard (Berger *et al.*, 1998; Murphy *et al*., 2004; Royster *et al.*, 1996). Subsequently, an additional interlaboratory study evaluating six hearing protectors in six different laboratories was conducted, and the results led to refinements in the methods of ANSI/ASA S12.6-2008 as compared to the 1997 document (Murphy *et al*., 2006).

The importance of human-factors considerations

Experimenter-supervised fitting of HPDs (i.e., carefully controlled placement of the devices), which was the only option in the 1984 version of ANSI S12.6 and one of two options in the 1997 version, is intended to describe the upper limits of hearing protector performance. This procedure can be useful for developing a better theoretical understanding of how hearing protectors block sound and interface with the head or earcanals. However, such data provide inadequate insight into the performance of HPDs when real-world human-factors considerations are taken into account. Since the seal between the HPD and the head or earcanal is such a critical determinant of the achieved attenuation, and because it is so strongly controlled by the subject and how the device is worn (especially for earplugs), human-factors considerations must be included in the laboratory model if valid field estimates are to be obtained.

In recognition of the importance of the HPD-head/earcanal interface, standardized laboratory methods of measuring hearing protector attenuation have typically involved the use of human subjects wearing the devices under test. Using human subjects as opposed to acoustical test fixtures is of great value because it provides the potential to develop a laboratory-based procedure that more closely models use conditions.

In spite of the importance of using human subjects, one must also consider that an experimenter interacting with listeners may lead to variability in measured results. The experimenter can dramatically influence the data by how s/he selects, trains, supervises, motivates, and fits the subjects—in short, by the experimenter's own preconceptions about how the HPD should be used and is expected to perform. The usefulness of the laboratory data in predicting field performance in a given application will be determined in large part by the degree of correspondence between the laboratory procedures for fitting HPDs and those found in the real world.

Definition of validity and selection of test methods

In order to create a procedure that generates "valid" data, the question has to be asked, "Valid with respect to what?" In practice, a wide range of HPD attenuation values may be observed in the workplace, from essentially no attenuation at all for devices incorrectly and inconsistently fitted by untrained users, to much higher levels of protection that may be obtained by well-trained and motivated users in workplaces with the most successful hearing conservation programs. It is unrealistic to use trained-subject fit values to estimate field performance for groups of workers in hearing conservation programs without recognition of the exceptional training under which they were obtained. Neither does it make sense to derate hearing protector performance to estimate worst-case attenuation values, since worst-case values are much more heavily influenced by factors other than the hearing protectors themselves.

The most suitable laboratory method will be dictated by the purpose to which the data will be applied. Thus, the choice made in the development of the 1997 version of this standard and retained in the current version was to provide two different but realistic fitting methods, one similar to the experimenter-supervised fitting procedure with which much of the hearing protection community has become familiar, and another for estimating representative field attenuation.

Method A of this standard, previously called "experimenter-supervised fit" and now designated "trained-subject fit," describes something close to an optimum fitting scenario that can be accomplished by a motivated and proficient user. In the current standard it allows full training and intervention by the experimenter as before, but for the actual test the subject must don the hearing protector on his or her own without assistance. The rationale is that allowing intensive individualized training immediately prior to a subject fitting the device is a reasonable reflection of the best that could be obtained in practice. The reason to not have the experimenter actually fit the device was the observation that experimenters, who vary in the way they interpret the standard and perform HPD fitting, can add substantial interlaboratory variability (Murphy *et al*., 2006). Isolating them from the actual test, to some extent, reduces this problem. Furthermore, in actual use workers and other users don hearing protectors on their own without assistance.

To estimate field performance, the Method-B approach of the 1997 standard was retained but re-designated "inexperienced-subject fit" to more clearly indicate the key feature of the procedure. Various details of the test method were refined with the aim of reducing ambiguity in interpretation of the dictates of this standard and to improving reproducibility. Method B is intended to approximate "achievable" results for workers in hearing conservation programs. Because in an inexperienced-subject fit procedure the experimenter's input is limited, much depends upon the subjects' skill in reading and interpreting instructions, which in turn is substantially affected by their prior experience with HPDs and any previous training they may have received. The literature suggests that under such conditions, it is important to select subjects with as little prior practice and training in HPD usage as possible; otherwise, their performance on the current tests will likely be strongly influenced by their preconceptions and acquired level of skill (Berger, 1992).

It was recognized that sincerely interested and/or highly motivated *individuals* may obtain workplace attenuation values significantly exceeding laboratory inexperienced-subject data, but for most populations of occupational users, the inexperienced-subject fit estimates will be more appropriate. The validity of the estimates was assessed and substantiated by comparing laboratory-measured values arrived at using the subject-fit protocol of this standard to values for groups of users derived from more than 20 available real-world studies (Berger *et al*., 1998).

Based upon the available literature as well as the findings of the 1990s interlaboratory study that provided the foundation for this standard (Berger *et al*., 1998; Royster *et al.*, 1996), it was anticipated that Method-A fitting would result in higher mean attenuation values and lower within-test standard deviation values than Method-B results, with the effect being substantially larger for earplugs than for earmuffs because of the greater importance of fitting factors in testing insert devices. See Annex A for examples of representative data. The results of the second interlaboratory study confirmed these findings but illuminated unanticipated problems with between-laboratory variability for both Methods A and B (Murphy *et al.*, 2006). This was one of the reasons for the conversion in this current standard from experimenter-supervised to trained-subject fit for Method A, and for many of the changes that were implemented in the Method-B protocol. See Annex A for information on the precision of the Method-A and Method-B procedures.

The choice of the method will be determined by the application that the user intends. For guidance, see Clause 1.2.

Beyond laboratory testing

The inexperienced-subject fit method described in this standard was developed to approximate the real-world attenuation achieved on average by most *groups of users* participating in actual hearing conservation programs; selected individual users may well achieve higher values. Attempts to predict values of attenuation achieved by individuals will have a large degree of uncertainty. The only way to make such predictions is to utilize field test measurements on the actual users in question. For a particular workplace the best way to estimate the attenuation actually attained by employees is to measure real-ear attenuation for the workers in question (Berger, 1986), or utilize field measurement devices to evaluate a sample or, preferably, the entire workforce. Ultimately, the audiometric database for the noise-exposed employees will demonstrate whether their hearing has been protected, but this bottom-line indicator depends upon the effectiveness of the entire hearing conservation program, not hearing protector use alone (ANSI S12.13 TR-2002).

American National Standard

Methods for Measuring the Real-Ear Attenuation of Hearing Protectors

1 Scope

1.1 Scope

This standard specifies laboratory-based procedures for measuring, analyzing, and reporting the passive noise-reducing capacity of hearing protection devices. The methods consist of psychophysical tests conducted on human subjects to determine real-ear attenuation at threshold.

Two methods are provided, differing in their subject selection, training, hearing protector fitting procedures, and experimenter involvement, but corresponding in all electroacoustic and psychophysical aspects. One method, designated *trained-subject fit*, is intended to describe the upper limits of hearing protector performance for devices fitted by carefully trained users. The second method, designated *inexperienced-subject fit*, is conducted with persons with little or no experience with respect to the use of hearing protection. It approximates the attenuation that has been achieved by groups of users as reported in real-world occupational studies (Berger *et al*., 1998).

1.2 Applications

The selection of test method, trained-subject fit or inexperienced-subject fit, is based upon the intended application.

Method-A trained-subject fit will correspond most closely to tests using the prior versions of this standard, issued in 1984 and 1997, and its predecessor, ANSI S3.19-1974. Such values are useful to estimate performance for highly trained and motivated individual users, as well as in the design of hearing protectors, to provide a theoretical understanding of their performance limitations, and for routine testing for quality assurance purposes.

Method-B inexperienced-subject fit is intended to provide an approximation of the upper limits to the attenuation that can be expected on average for *groups* of occupational users. Properly trained and motivated *individuals* can potentially attain larger amounts of protection, in closer agreement with the trained-subject fit data, especially for earplugs, than the inexperienced-subject fit values found using this standard. However, inexperienced-subject fit values provide a closer correspondence to real-world performance for groups of users than do the trained-subject fit data.

Regardless of the test method that is selected, trained-subject fit or inexperienced-subject fit, the attenuation values will be applicable only to the extent that:

(a) the hearing protectors are worn in practice in the same manner as during the laboratory test;

(b) the hearing protectors are properly maintained; and

(c) the anatomical characteristics of the population of actual wearers are a reasonable match to the laboratory test subjects.

The methods of this standard apply to passive hearing protectors, as well as to electronic devices when the electronics are turned off. Hearing protectors can also take the form of communications headsets and earplugs, helmets, pressure suits, and other systems with sound-attenuating features. Devices can be used in combination with one another, such as earplugs worn in conjunction with earmuffs or helmets.

The methods of this standard yield data that are collected at low sound pressure levels (close to the threshold of hearing) but which are also representative of the attenuation values of hearing protectors at higher levels. One exception occurs in the case of passive amplitude-sensitive hearing protectors for sound pressure levels above the point at which their level-dependent characteristics become effective. At those levels the methods specified in this standard are inapplicable; they will usually underestimate sound attenuation (Berger, 1986). Another exception exists with respect to predicting the noise reduction of high-level impulsive sounds such as from weapons fire, over 140 dB peak sound pressure level, because of possible level-dependent behavior of hearing protectors when exposed to such sounds.

The low-frequency (below 500 Hz) real-ear attenuation at threshold data resulting from this standard may be spuriously high by a few decibels, with the error increasing as frequency decreases. This results from masking of the occluded-ear thresholds caused by physiological noise during testing (Berger and Kerivan, 1983; Schroeter and Poesselt, 1986). The errors are largest for semi-insert and supra-aural hearing protectors, for small-volume earmuffs, and for shallowly inserted earplugs. The errors are smallest for large-volume earmuffs and more deeply inserted earplugs.

This standard does not address issues pertaining to computation of protected noise exposures or rating systems for applying hearing protector attenuation values (see ANSI/ASA S12.68), nor does it specify minimum performance values for hearing protectors, or address comfort or wearability features.

2 Normative references

The following referenced documents are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ANSI S1.1, *American National Standard Acoustical Terminology*

ANSI S1.11-2004, *American National Standard Specification for Octave-Band and Fractional-Octave-Band Analog and Digital Filters*

ANSI S3.1-1999 (R2003), *American National Standard Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms*

ANSI S3.6, *American National Standard Specification for Audiometers*

ANSI S3.20, *American National Standard Bioacoustical Terminology*

ANSI S3.36-1985 (R2006), *American National Standard Specification for a Manikin for Simulated in-situ Airborne Acoustic Measurements*

ANSI/ASA S12.68, *American National Standard Methods of Estimating Effective A-Weighted Sound Pressure Levels When Hearing Protectors are Worn*

NOTE "R" stands for reaffirmed.

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in ANSI S1.1, ANSI S3.20, and the following apply:

3.1 amplitude-sensitive hearing protection device. A hearing protector, also referred to as a level-dependent hearing protector, that is designed to exhibit a change in attenuation as a function of sound level.

3.2 earmuff. A hearing protector usually comprised of a headband and earcups with a soft cushion to seal against the head, intended to fit against the pinna (supra-aural) or the sides of the head around the pinna (circumaural). The earcups may also be held in position by attachment arms mounted on a hard hat or hard cap.

3.3 earplug. A hearing protector that is inserted into the earcanal.

3.4 hearing protection device (HPD). A personal device, also referred to as a hearing protector, worn as a barrier to reduce the sound level entering the earcanal in order to diminish the harmful auditory and/or annoying subjective effects of sound.

3.5 helmet. A device, sometimes functioning as a hearing protector, which usually covers a substantial portion of the head, that may include internally mounted earcups and/or earplugs.

3.6 occluded threshold of hearing. At a specific frequency, the minimum effective sound pressure level of the signal that is capable of evoking an auditory sensation in a specified fraction of the trials when the hearing protector under test is worn.

3.7 open threshold of hearing. At a specific frequency, the minimum effective sound pressure level of the signal that is capable of evoking an auditory sensation in a specified fraction of the trials when a hearing protector is not worn (i.e., ears unoccluded).

3.8 passive hearing protection device. A hearing protector that relies solely on its mechanical elements to block or otherwise control the transmission of sound to the auditory system.

3.9 pink noise. Noise for which the spectrum density varies as the inverse of frequency.

3.10 random incidence. Incidence of sound waves from all directions with equal probability.

3.11 real-ear attenuation at threshold (REAT). At a specific frequency, the mean value (in decibels) of the occluded threshold of hearing minus the open threshold of hearing on all trials under otherwise identical test conditions, either for a single listener or averaged across a group of listeners.

3.12 reference point. A fixed spatial location within the test chamber at which the midpoint of a line connecting the test subjects' earcanal openings is located for REAT measurements, and likewise the point to which all objective measurements of the sound field characteristics are referenced.

3.13 requester. The party submitting a hearing protection product and fitting instructions for testing.

NOTE When the investigator is evaluating hearing protectors other than for an entity external to the laboratory, the requester is considered to be the investigator conducting the research.

3.14 reverberation time. Of an enclosure, for a stated frequency or frequency band, the time required for the level of the time-mean-square sound pressure in the enclosure to decrease by 60 dB after the source has stopped. Unit, second (s).

3.15 semi-insert device. An earplug-like device (also called canal cap or concha-seated hearing protector) consisting of soft pods or tips that are held in place by a lightweight band. The pods are positioned in the conchae covering the entrances to the earcanals, or fitted to varying depths within the earcanals. Semi-inserts that cap the canal require the force of the band to retain their position and acoustic seal. Semi-inserts that enter the canal behave more like earplugs; they seal the ear to block noise with or without the application of band force.

3.16 white noise. Noise for which the spectrum density is independent of frequency.

4 Physical requirements of the test facility

4.1 Test signals

Test signals shall consist of pink or white noise, filtered into one-third octave-bands. Center frequencies shall include at least 125, 250, 500, 1000, 2000, 4000, and 8000 Hz.

4.2 Test site

4.2.1 Diffuse sound field requirements

4.2.1.1 Uniformity

The sound pressure level measured using an omnidirectional microphone at six positions relative to the reference point, with the subject and the subject's chair absent, ±15 cm in front-back, up-down, and left-right axes, shall remain within a range of 5 dB for each test signal. The difference between the left-right positions shall not exceed 3 dB. The orientation of the microphone shall be kept the same at each position.

4.2.1.2 Directionality

The directionality of the sound field shall be evaluated at the reference point for test bands with center frequencies greater than or equal to 500 Hz, with the subject and the subject's chair absent. The measurements shall be conducted with a directional microphone that exhibits in its free-field polar response at the one-third octave test bands, at least 10 dB front-to-side rejection for a cosine microphone, or at least 10 dB front-to-back rejection for a cardioid microphone.

The sound field shall be considered to approximate a random incidence field if, when the microphone is rotated at the reference point through 360 degrees in each of the three perpendicular planes defined by the front-back, up-down, and left-right axes coincident with the reference point, the observed sound pressure level in each test band remains within the variation allowed in Table 1 when the measurements are evaluated separately for each plane. The sound pressure levels may also be obtained by measuring at fixed 15-degree increments as the microphone is rotated 360 degrees in each plane.

4.2.2 Reverberation time

The reverberation time at the reference point, with the subject and the subject's chair absent, shall not exceed 1.6 s for each test signal.

Table 1 — Allowable variation of sound-field sound pressure levels within each plane, for corresponding directional microphone free-field rejection

Microphone free-field rejection, dB	Allowable variation, dB [a]
≥ 25	6
20	5
15	4
10	3
< 10	microphone not suitable

[a] For directional microphones whose free-field rejection values fall between those values in the table, the allowable variation shall be computed by linear interpolation.

NOTE The variation in microphone response as the microphone is rotated in a random incidence field is related to the directional characteristics of the microphone and the degree of randomness of the field being measured. Thus, allowable sound field response variations are related to the free-field directional response characteristics of the microphone. The microphone characteristics may be obtained by measurement in a free field or from the microphone manufacturer.

4.2.3 Ambient noise

The ambient noise at the reference point, with the subject absent, and with all signal presentation equipment on and adjusted to a gain of 20 dB above the levels necessary to elicit the average open threshold of hearing for the group of test subjects at all test frequencies, but with no test signal present, shall not exceed the octave-band levels in Table 2. Ambient noise levels shall be measured at least monthly, or more often if the laboratory conditions warrant. All ventilation and lighting shall be set as would be normal during threshold testing. The noise floor in each frequency band shall be calculated from the median of five measurements made at least 15 minutes apart on the same day or on different days within the past year.

If any extraneous noise becomes audible in the test room during testing, the listener shall signal the experimenter to stop the test. Once the noise has stopped, the test shall resume for a test frequency prior to which the disruption was first noted.

Table 2 — Maximum permissible ambient noise at the reference point

Frequency, Hz	Octave-band SPL, dB [a]
31.5	57.0
63	43.0
125	29.0
250	21.0
500	16.0
1000	13.0
2000	14.0
4000	11.0
8000	14.0

[a] Values re 20 μPa

NOTE 1 Levels are taken from ANSI S3.1-1999, Table 3, ears not covered, 125 to 8000 Hz. Levels at 31.5 and 63 Hz are taken from Table C.3 of that same standard, ears not covered, 125 to 8000 Hz.

NOTE 2 Any audible noise during testing may be distracting or may cause masking over a portion of the range of test signals. This will elevate the open threshold of hearing and result in erroneously small values of real-ear attenuation for the device under test. Many rooms that cannot meet the ambient noise requirements in Table 2 on a continuous basis will be suitable if test periods are selected during times that do meet the requirements.

4.3 Test apparatus

The test apparatus shall include a noise generator, one-third octave-band filter set, control circuits (on-off switch and calibrated attenuators), power amplifier(s), loudspeaker(s), and a head-positioning device. Computer noise generation, filtering, and control is also acceptable.

4.3.1 Test signal (1/3-octave band of noise)

The test signals, as measured electrically at the speaker terminals, shall consist of one-third octave bands of pink or white noise, with a spectrum shape equivalent to that which would be created by a filter meeting the requirements of ANSI S1.11-2004, Class 0. The mode of operation in changing from one band to another shall be a discrete step function; a gradual continuously adjustable mode of change is not acceptable.

4.3.2 Dynamic range

The test apparatus shall be able to generate test signal sound pressure levels at the reference point, for any test band, that vary from at least 10 dB above the subject's occluded threshold of hearing to 10 dB below the subject's open threshold of hearing. For most hearing protectors this is equivalent to a level of 60 dB above to 10 dB below the open threshold of hearing.

NOTE The level of 10 dB below the threshold of hearing may be calculated on the basis of electrical calibration.

4.3.3 Distortion

When the test apparatus generates 1/3 octave-band test signals at the reference point, at sound pressure levels which comply with Clause 4.3.2, the sound pressure levels shall be at least 6 dB down from the maximum level in adjacent 1/3 octave bands, at least 30 dB down in 1/3 octave bands one octave or more removed from the center frequency, and at least 40 dB down in 1/3 octave bands two octaves or more removed from the center frequency. During the test, the sounds shall be reproduced without audible buzzing, crackle, or rattle.

4.3.4 Control circuits

Attenuators shall have a range of at least 90 dB for each test signal, with a step size of ≤2.5 dB.

The difference in output between any two attenuator settings, measured with a pure-tone test signal, shall not differ from the indicated difference by more than 3/10 of the indicated increment or by 1 dB, whichever is smaller. Corrections for departure from linearity shall be applied to the data when this requirement is not met. Where possible this test shall be performed acoustically. When the ratio of the acoustically measured sound pressure level to the ambient background noise is less than 20 dB, the linearity of the signal voltage shall be measured at the terminals of the loudspeaker(s).

4.3.5 Signal pulsing

Test signals shall be pulsed between 2 and 2.5 times per second, with a 50% duty cycle, and without audible clicks, pops, or other transients. When exciting the system with pure tones at the test signal center frequencies, the on-phase (the time the signal remains within 1 dB of its maximum level) shall be greater than 150 ms, and the output during the off-phase shall reach at least 20 dB below the maximum levels, as measured electrically at the speaker terminals.

4.3.6 Fitting noise

The fitting noise shall be a broadband random noise presented at an overall A-weighted sound pressure level of approximately 70 dB (re 20 μPa) at the reference point. A higher level of fitting noise may be used for extremely high attenuation devices or systems.

4.4 Head-positioning device

A head-positioning device, such as a plumb bob to the nose or the forehead of the subject, shall be used to maintain the subject's head at the reference point. A headrest or bite bar is not acceptable. The device shall not transmit vibrations to the head that affect the threshold measurements, and shall not measurably affect the uniformity of the sound field of the room as specified in Clause 4.2.1.1.

4.5 Observation of subjects during testing

The test room shall be equipped with a viewing window or video system to allow clear observation of the subject at all times during the test.

5 Test subjects

5.1 Anatomical features

Subjects shall be selected without respect to sizes and shapes of heads, pinnae, or earcanals unless the requester indicates that the product is intended for use by specific populations such as children. However, subjects shall be excluded for features or physical disabilities adversely affecting the fitting of hearing protectors, such as might arise from birth defects, ear surgery, or personal adornments.

5.2 Otoscopic inspection

At the time of initial audiometric testing, subject's ears, as determined by an otoscopic inspection, shall be free from conditions that would affect the fit of the hearing protector, such as excessive cerumen, irritation, or infection. This requirement shall also apply to areas of the pinna and head that would be contacted by the hearing protector being tested.

5.3 Measurement of earcanal size and head dimensions

Prior to audiometric qualification and participation in attenuation testing, the dimensions of both the right and left earcanals, and the bitragion width and head height of the test subject shall be measured per the procedure of Annex B. In the case of Method-B testing, the subject shall *not* be told that her or his earcanals are being sized, nor shall s/he be advised of the results of the size determinations until such time as s/he is no longer involved in the facility's Method-B hearing protector attenuation studies.

A suitable explanatory phrase to tell the subjects is:

> *"I am going to inspect your ears and measure your head using standard evaluation devices."*

NOTE If a laboratory is certain at the time of qualification of their subjects that they will only be participants in tests of earplugs (i.e., devices without bands), then head dimensions need not be measured. Likewise, earcanals need not be measured if subjects will only be used for tests of earmuffs and helmets.

5.4 Gender balance

Unless the hearing protector under test is intended by the requester for use by only males or females, the ratio of male to female subjects shall be between 60/40 and 40/60.

5.5 Hearing sensitivity

5.5.1 Minimum sensitivity

Subjects shall have pure-tone air-conduction hearing threshold levels at the octave-band center frequencies from 125 Hz to 8 kHz, as measured using a standard audiometer, that are ≤25 dB (ANSI S3.6).

5.5.2 Maximum sound-field sensitivity relative to room ambient noise

No subject shall be used whose 1/3 octave-band open thresholds of hearing measured in the sound field of the test room, averaged across two determinations, are more than 3 dB below the octave-band ambient noise levels at any test frequency from 125 Hz to 8000 Hz.

NOTE The limitations on open threshold sensitivity relative to test-room ambient noise levels are intended to reduce the potential for the elevation of the open thresholds due to masking. If masking occurs, it would tend to decrease the mean attenuations and possibly also increase the standard deviations.

5.6 Threshold variability (during qualification)

Subjects shall be trained with a minimum of five open-ear sound-field audiograms (separate from those utilized for attenuation testing), administered all in one session, the last three of which shall be checked for variability. The range in the open threshold of hearing for each frequency shall not exceed 6 dB. Additional practice audiograms can be administered in the same or subsequent sessions until the subject either meets the 6-dB requirement or is rejected.

5.7 Eyeglasses and jewelry

Subjects shall not wear eyeglasses, ear jewelry, or other accessories that might affect the ability of the hearing protector to make an acoustical seal, unless specifically designated by the requester.

5.8 Number of subjects

At least ten subjects shall be used for each test on earmuffs or helmets. At least twenty subjects shall be used for each test on earplugs, semi-insert devices, earmuffs attached to hard hats, or when a combination of an earplug and an earmuff are being tested.

6 Product samples

6.1 Minimum number of samples

For formable earplugs (such as foam-tipped or roll-down foam earplugs) a minimum of three pairs of earplugs per test subject shall be provided, or, if the product is available in sizes, three pairs of each product size for each subject shall be provided. A new pair shall be used for training and each occluded trial. For other types of earplugs and semi-insert devices a minimum of one pair or device per test subject shall be provided, or, if the product is available in sizes, one of each product size for each subject shall be provided. When sized products are tested, different sizes may be used for each ear. Once testing has begun, subjects shall continue to utilize the same size product as initially selected for all repeat fittings in a given study.

For earmuffs there shall be a minimum of one pair of earmuffs for every two subjects.

For earmuffs that attach to hard hats there shall be a minimum of one pair for every four subjects and sufficient samples of the hard hats such that once a pair of earmuffs is attached to a hard hat, it shall not be removed or replaced. The specific model of hard hat shall be specified by the requester and sufficient samples in each of the sizes in which it is offered, to correspond to the number of earmuff pairs that are being tested, shall be provided. For each size of hard hat, one additional sample shall be provided, along with a corresponding pair of earmuffs, for force measurements according to Clause 10.1. The experimenter shall assist in selecting the appropriate size hard hat for each subject. As an example, for a 20-subject test on an earmuff that attaches to a hard hat that comes in a single size, the requester shall provide six pairs of earmuffs and six hard hats.

For helmets there shall be a minimum of one sample for each size utilized in the testing.

6.2 Devices with variable band force adjustments

Earmuffs and semi-insert devices with bands or attached to hard hats that include adjustment mechanisms allowing the band force to be varied shall be initially set to the minimum application force of their adjustment range prior to being provided to each subject. During fitting, the devices may be readjusted per the provisions of Clauses 8.1 or 9.2.

6.3 Special requirements for inexperienced-subject-fit method

Products shall include complete on-package instructions in the exact format (i.e., same presentation media, text, as well as the same wording, size, color, and contrast) as would be provided to a purchaser of the product. No additional instructions are permitted unless they would normally accompany the product when sold in commerce. No video training instructions on fitting and use of the device under test, or access to websites shall be permitted.

7 Psychophysical procedure

7.1 Informing the subject

Subjects shall be completely informed regarding the test situation and procedure, and that they can withdraw from the test at any time for any reason. They shall also be informed of the need to alert the experimenter if at any time during testing they hear an extraneous noise.

7.1.1 Additional information for participants in inexperienced-subject fit tests

Subjects participating in Method-B measurements shall be informed as follows:

> *“Because I do not want to influence the choices you will be making in the hearing protector evaluations, I cannot tell you any of your test results as long as you are a subject in this laboratory. After you complete your work as a participant on our subject-fit test panel, I will be pleased to share with you any of your results."*

7.2 Positioning the subject

The subject shall be seated in such a way that, using the head-positioning device (see Clause 4.4), his or her head will be placed and maintained at the reference point (see Clause 3.12) for all repeated measurements.

7.3 Number of open and occluded threshold measurements

The attenuation for each subject at all test frequencies shall be measured on two trials during a single visit to the laboratory. Each trial shall consist of a paired open and occluded threshold, the order being counterbalanced across subjects. An example of the sequence of threshold testing is provided below. The two thresholds that comprise a given trial for each subject are the first pair of open and occluded thresholds and the second pair of open and occluded thresholds, respectively.

Representative testing sequence

	One-half of the subjects	One-half of the subjects
Trial 1	Occluded, open	Open, occluded
Trial 2	Occluded, open	Open, occluded

The hearing protector shall be refitted for each trial. Although a rest period may be provided between trials, the subject shall not leave the chamber during a trial, i.e., between pairs of open and occluded thresholds.

7.4 Threshold measurement method - Békésy tracking procedure

The test signal shall be discrete frequencies as defined in Clause 4.1, and the threshold measurement procedure shall be a Békésy tracking procedure as described in this Clause. The stimulus level shall be increased or decreased incrementally in response to a control device operated by the subject, with a rate of change used for the threshold determination set at a value of from 2 to 3 dB/s. The implementation shall be identical for the open and occluded thresholds, and capable of producing the data required in Clause 11.1.

The thresholds shall be determined as follows:

1) A trace at a given frequency shall be repeated if, ignoring the first reversal following a change of frequency and occasional reversals associated with trace excursions of 3 dB or less:

    a) there are less than six reversals.

    b) any peak is lower than any valley.

    c) the range of excursions (any peak to valley difference) exceeds 20 dB.

2) Acceptable traces should be scored by ignoring the first reversal following a change of frequency and then averaging together an equal number of peaks and valleys of the tracing at a given frequency. Very similar results can be obtained more simply by “visual averaging,” in which a horizontal line drawn through the center of the tracing is used to estimate the average value.

NOTE For purposes of uncertainty analyses it is useful to capture and report the standard deviations of the midpoints of the excursions that comprise each threshold.

7.5 Open threshold variability (during testing)

If the range of open thresholds at any frequency during a test session exceeds 6 dB, the threshold at that frequency shall be retested until two open thresholds are measured that agree within 6 dB.

NOTE For example, the two usable open thresholds could be the Trial 1 open and the retest threshold from Trial 2, or some other combination.

7.6 Quiet period prior to first threshold measurement

In order to allow for accommodation to the test situation, subjects shall be seated in the test room, without talking to the experimenter and with no signals present, for a minimum of two minutes prior to the initial trial of a test session, after which time the threshold determinations may begin.

7.7 Waiting period subsequent to fitting hearing protector

To allow hearing protectors to expand or conform to fit the earcanal or circumaural regions, occluded threshold measurements shall begin a minimum of two minutes after the hearing protectors have been fitted, unless the requester’s written instructions specify that a longer minimum time is required.

8 Method A: trained-subject fit

The following clauses describe how to train test subjects in a consistent manner, when it is permissible to dismiss them from a test, and the specific Method-A testing procedures.

NOTE See Annex C for a checklist summarizing the specific steps and the sequence of events that are required to implement this method.

8.1 Training in fitting hearing protectors

The experimenter shall give each subject precise directions and practice in fitting the hearing protector in accordance with the instructions that are provided with the product to all users. The requester may provide additional publicly available guidance on training and fitting, including criteria defining what comprises an acceptable fit. The instructions shall not be modified by the experimenter’s own knowledge in fitting the same or similar devices. No indicators, marks, or lubricants shall be utilized (unless supplied and called for by the requester), nor shall any modifications be made to the devices to better aid in fitting or determining their correct fit. When applicable, the experimenter shall assist the subject in following the instructions to select the appropriate size hearing protector and in adjusting products with variable band force.

As necessary to clarify (without adding to) the training and fitting instructions, the experimenter shall provide explanation, demonstrations, and physical assistance. The experimenter shall train the subject in using the relative loudness of the fitting noise (Clause 4.3.6) to assist in the fitting process, and may personally fit the device to the test subject as part of the instruction process. However, trial sound attenuation measurements shall not be part of the sizing or fitting procedures unless they are included with the product or the product delivery process. There is no limitation on either the duration of the training or the number of practice fittings that may be attempted.

Once the experimenter has determined that the subject can properly put on the hearing protector and is fully satisfied that the subject understands and can correctly repeat the fitting process, the subject is ready to begin the attenuation test.

8.2 Conditions for subject dismissal

After training, a subject shall be dismissed if s/he cannot obtain an acceptable fit based on any one of the following criteria: 1) the subject's assessment of the quality of the seal by listening to the loudness of the fitting noise, 2) visual evaluation by the experimenter, 3) tactile evaluation by the experimenter working in conjunction with the subject, or 4) guidance specific to that product as provided in advance by the requester. Additionally, subjects who fail the requirements in Clauses 5.1 to 5.6, or who repeatedly fail the requirements of Clause 7.5, shall be dismissed. Subjects may be dismissed for illness or physical inability to participate on the day of the test or if they are unable to consistently remain attentive during threshold testing. Subjects shall not be retested or dismissed for the attenuation they obtain during the testing process.

8.3 Test procedures

For the occluded tests, the subject shall fit or don the hearing protector without the experimenter present in the test chamber. The experimenter shall observe the subject during the test from outside the chamber. After the hearing protector has been positioned, the fitting noise shall be introduced and the subject shall be told to manipulate the hearing protector to minimize the perceived noise. Once the subject is satisfied with the fit, and after observing the quiet period specified in Clause 7.6 and the waiting period specified in Clause 7.7, the test shall begin.

Adjustment of the fit of the hearing protector during the test trial shall not be allowed. However, the subject shall be instructed to inform the experimenter if, during the test, a change in fit of the device is noticed, and if so, the test shall be stopped. The subject shall then refit the device and the test shall be restarted from the beginning of the trial. If this occurs a second time, the test shall be completed without refit and the attenuation data shall be used in the computations specified in Clauses 11.1 and 11.2.

9 Method B: inexperienced-subject fit

The following clauses describe the allowable experience level of test subjects, how long they can be retained as subjects, how to prepare them for testing, and the specific Method-B testing procedures.

NOTE See Annex C for a checklist summarizing the specific steps and the sequence of events that are required to implement this method.

9.1 Conditions for subject acceptance/dismissal

There shall be *no* subject selection criteria besides those specified in Clauses 5.1 to 5.6, and 9.1.1 to 9.1.3. However, subjects may be dismissed for illness or physical inability to participate on the day of the test, or may be removed from the panel if they repeatedly fail the requirements of Clause 7.5. It is not permitted to optimize a test panel based upon experience gained from subject participation in prior tests.

9.1.1 Criteria for acceptance of inexperienced-test subjects

Measurements shall be conducted on subjects who are inexperienced with respect to the use of hearing protection as defined below. Subjects shall be rejected if they answer “yes” to a), b), or c), or if in response to d) they indicate use of earplugs or semi-inserts for more than 10 occasions or use of earmuffs for more than 20 occasions in the prior two years.

a) Have you *ever* received one-on-one personal instruction in the fitting of hearing protectors?

b) Within the past two years, have you received group instruction on, or watched videotaped or computer-based instruction about, how to fit hearing protectors?

c) Within the past two years, have you participated in an experiment involving the use of hearing protection?

d) Within the past two years, on how many occasions have you worn hearing protectors because you were exposed to noise as part of your occupation, military duty, or other activity, and how many times have you worn earplugs while sleeping or swimming?

9.1.2 Literacy

Subjects shall demonstrate a level of literacy sufficient to be able to read and understand hearing protector instructions and any informed consent forms required for use by the test laboratory.

9.1.3 Limitations on subject retention and reuse

Once a subject has been accepted in an inexperienced-subject fit evaluation in a given facility, s/he may participate for a lifetime maximum of 30 separate inexperienced-subject fit tests, each test consisting of 2 trials. Of those 30 tests, the total number permissible for earplugs and semi-inserts, or both, shall not exceed 12, and there shall not be more than 4 tests on any one of the following categories: foam, premolded, malleable, semi-insert, and other earplugs, and no more than one test on a custom-molded plug. Subjects shall be excluded from any further inexperienced-subject fit testing of earplugs or semi-inserts once they have viewed video or computer-based fitting instructions during a product test.

As a condition of reuse in inexperienced-subject fit experiments, subjects shall receive *no feedback* regarding how they have done on particular attenuation tests. If subjects inquire, they shall be reread the information statement in Clause 7.1.1. Furthermore, to guard against subjects receiving any further training or experience during their tenure as a participant in inexperienced-subject fit testing, they shall be asked prior to the test session, but no more than once each week, to reaffirm 9.1.1 a), b) and d), with respect to experience gained outside the laboratory environment. Criteria for rejection shall be the same as in 9.1.1.

Once a subject no longer qualifies for inexperienced-subject fit testing due to the requirements of this clause, s/he may still participate in trained-subject fit tests.

9.2 Test preparation

The instructions for the inexperienced-subject fit method are explicit and shall be followed in every detail. The *italicized passages* in quotations shall be read aloud, verbatim, to the subject while s/he follows the printed text.

9.2.1 Prior to entering test chamber

Prior to entering the test chamber, the subject shall be handed the hearing protector in the packaging in which it is sold or an equivalent mockup (same color, contrast, and font size), along with the requester's written fitting instructions that would normally accompany the device. Devices with variable band force adjustments shall be initially set to their minimum (Clause 6.2). The subject shall be instructed as follows:

> *"The purpose of this test is to estimate the noise reduction that you would be likely to achieve while wearing this hearing protector in a noisy environment. In a moment I will ask you to read the instructions and fit and adjust the hearing protector to the best of your ability. I am not allowed to assist you in that process or provide any feedback. When you are finished reading, I will ask you to repeat the instructions in your own words and to describe the important features of any illustrations that are included."*

The subject shall be advised of the existence and location(s) of all available requester's fitting instructions, on and/or inside the individual product packaging or master dispenser. The subject shall fit and adjust the hearing protector in both ears without any verbal or physical assistance from the experimenter. When semi-inserts or earmuffs are tested that have headbands that can be worn in more than one position, such as over the head or behind the neck, the experimenter shall advise the subject of the position to be utilized for the test being conducted. No fitting noise shall be provided during the test preparation prior to entering the test chamber.

For hearing protectors that are supplied in multiple sizes, one pair of each size shall be placed on a table in front of the subject at the time that s/he is given the requester's written fitting instructions. Before the subject reads the requester's instructions, the experimenter shall say:

> *"Please try these protectors on to find the size that is best for you based on the instructions provided."*

The experimenter shall not provide recommendations or physical assistance, present a fitting noise, nor utilize sound attenuation measurements in the size selection process. Exceptions occur in the following serious cases of misuse: 1) an earplug inserted backwards or sideways, 2) earplugs that have right and left designations that are inserted in the incorrect ears, or 3) head or neckbands that are worn in other than the nominally designated position. In this case the error is pointed out to the subject and they are asked to reread the instructions.

The total fitting process, from the time the subject begins to read the requester's instructions and fit the hearing protector until s/he enters the chamber for testing, shall not exceed 10 min. If necessary, subjects shall be advised after 8 min. have expired that they shall make their best attempt at fitting the hearing protector within the next 2 minutes.

Once the subject indicates that the fitting has been completed, or 10 min. have expired, s/he shall remove the hearing protector and enter the test chamber.

9.2.1.1 Insertion-assistance devices

If any type of insertion-assistance device or seating tool (such as a cylinder to slide over the flexible stem of a multi-flanged earplug, or a rigid core to slide into an open-backed earplug) is provided by the requester, its use by the subject shall be treated as any other aspect of the instructions. The subject shall be handed the insertion assistance device along with the hearing protector, and shown the requester's written directions. Whether or not the insertion-assistance device is used is up to the subject, not the experimenter.

9.2.1.2 Custom-molded earplugs

With these types of earplugs, which of necessity require direct physical involvement between the experimenter and the subject in order to take the impression, the requester's instructions shall be followed explicitly. Ear impressions shall be made by the experimenter unless the requester's instructions normally accompanying the product, or the product delivery process itself, indicate that a requester's representative shall be involved in the process.

Once the earmold is completed, or received back from the requester ready for testing, it will be provided to the subject as would any other earplug, with only the requester's written instructions, unless the product delivery process or the written instructions specify that a fitter is required to individually fit and train the subject.

NOTE As with all aspects of the subject-fit procedure, the experimenter is not to augment requester's instructions. If the requester fails to require use of an eardam, the experimenter shall not use one in taking the impressions for testing, unless this contravenes the standard practices of the test laboratory or the licensure laws of the state in which the lab resides, in which case the test will have to be declined. Even if the test is accepted by the laboratory, the requester shall be informed concerning the hazards of taking impressions without eardams and offered the opportunity to modify its instructions accordingly.

9.2.1.3 Earmuffs attached to hard hats

The experimenter shall begin by adjusting the hard hat suspension so that the hat is secure and the webbing of the hat rests on the top of the head. The earmuff cup/attachment arm assemblies shall be installed on the test hard hat prior to presenting the units to the subjects for practice fitting and testing.

9.2.1.4 Helmets

When fitting helmets with adjustable suspension systems, there is no time limit for the fitting process.

With helmets that require direct physical involvement between the experimenter and the subject in order to properly fit the device, the requester's instructions shall be followed explicitly. Once the helmet is properly customized and/or adjusted, it will be provided to the subject as would any other hearing protector, with only the requester's written instructions.

9.3 Test procedure

The following procedures take place inside the test chamber. The sequence will vary slightly depending on the order of open and occluded thresholds.

9.3.1 Beginning the testing (occluded threshold first)

The subject enters the chamber with the protector to be tested. Instructions and packaging shall not be brought into the chamber. The subject is seated and prior to fitting the hearing protector, the experimenter shall instruct the subject as follows:

> *"After I leave the chamber I will turn on a noise to indicate that you should put on the hearing protector. Please do so using the requester's instructions and the experience you have gained in practice. Once you indicate that you have completed fitting the protector I will turn off the noise, and after two minutes the test will begin. You may not touch or adjust the protector until you are asked to remove it at the end of the test. If the device comes loose during the test, please signal me. Throughout the test I will be able to observe you through the window [or, using the TV camera]."*

NOTE The experimenter does not indicate to the subject the type or purpose of the noise that is presented.

After reading the preceding statement to the subject, the experimenter shall leave the chamber and shall introduce the fitting noise as defined in Clause 4.3.6. S/he shall not be present during the final fitting process **nor shall any assistance or additional explanations be provided at that time.** The subject shall be allowed a maximum of 5 min. to fit the hearing protector or a maximum of 8 min. when a combination of an earplug and earmuff or helmet are being tested. The appropriate quiet and waiting periods shall be observed per Clauses 7.6 and 7.7.

9.3.2 Beginning the testing (open threshold first)

The procedure is the same as in Clause 9.3.1 except that once the subject is seated, the experimenter instructs the subject to sit quietly, and leaves the chamber so that a 2-minute quiet period can be observed (per Clause 7.6). Once the open threshold is completed, the experimenter returns and follows the instructions as in Clause 9.3.1.

9.3.3 During the test

Once the test has begun, regardless of the fit of the hearing protector, the data shall be accepted. However, if the hearing protector loses its fit to an extent that would in ordinary circumstances of use cause the wearer to readjust its position, the subject shall notify the experimenter who shall then terminate the test. The experimenter shall enter the chamber and ask him or her to refit the device for a retest following the procedures given in Clause 9.3.1. If the hearing protector loses its fit a second time, testing shall again be terminated, and the subject shall be replaced.

If a second type of hearing protector is tested during the same visit, the subject shall exit the chamber and begin the process in the same manner as during the test of the first hearing protector.

10 Band application force

The force shall be measured on all samples of earmuff and semi-insert devices prior to attenuation testing. This requirement does not apply to helmets. Force shall be measured two minutes ±5 s after the hearing protector has been positioned on the test fixture, and the values reported in newtons (N). The temperature and relative humidity at which the band force is measured shall be recorded.

NOTE The laboratory may devise its own band force measuring device or may purchase a suitable unit.[1]

10.1 Earmuffs

The force exerted by earmuffs shall be measured on a suitable fixture with hard flat plates against which the earmuff cushions are pressed. The plate separation shall be 145 mm ±1 mm [median head width (bitragion width)], with a distance of 130 mm ±1 mm between the inside of the headband and an imaginary line through the pivot points of the attachments of the headband to the earcups (median head height). The headband shall remain free during the measurement. For some types of products, such as those with headbands situated behind the neck or under the chin, other head-height dimensions may be more appropriate. The actual dimensions shall be reported. For products with a variable band force adjustment, the device shall be adjusted to the midpoint of its range.

[1] Suitable units are available from Michael and Associates, Inc., State College, PA, or INSPEC Laboratories, Ltd., Salford, UK. Equivalent units from other sources may be used.

To test the force of earmuffs that are attached to hard hats, the support webbing shall be removed from the inside of the hard hat and a hole drilled through its vertex so that the hat can be positioned on a stud affixed to the test fixture in a reproducible manner. The test fixture head height and earcup separation shall be adjusted as for standard earmuff assemblies.

10.2 Semi-insert devices

The force exerted by semi-insert devices shall be measured on a suitable fixture having flexible pinnae, the dimensions of which are specified in Annex D. The bitragus breadth shall be 145 mm ±1 mm. The head/neck band shall remain free during the measurement. For semi-inserts with adjustable bands, the band shall be set for a head height of 130 mm ±1 mm, or its minimum setting, whichever is greater. For devices with asymmetric pods, the devices shall be properly oriented to fit the concha and earcanal entrance.

11 Processing and reporting the data

11.1 Recording the data

The data to be recorded, from which the hearing protector attenuation values are calculated, shall consist of either relative or absolute threshold values. Two open and two occluded threshold levels shall be recorded at each test frequency for each test subject.

11.2 Computation of real-ear attenuation

The measurements shall be summarized for at least each of the seven specified one-third octave-band test signals in terms of an arithmetic mean attenuation and a standard deviation. Real-ear attenuation at threshold for each listener shall be computed at each frequency by averaging the two trials, i.e., the two open/occluded threshold differences. The mean for the panel of subjects is the average of each of the individual two-trial subject averages. The standard deviations in decibels shall be computed as:

$$s = \sqrt{\frac{\sum_{i=1}^{N}(d_i)^2}{N-1}} \qquad (1)$$

where d is the difference between the average attenuation of each individual's two trials and the panel mean attenuation, and N is the number of subjects (≥ 10 for earmuffs or helmets and ≥ 20 for earplugs, semi-inserts, earmuffs attached to hard hats, or a combination of earplugs plus either earmuffs or helmets). N – 1 is used for purposes of computing an unbiased estimate of the population standard deviation.

11.3 Information to be included in test report

The test report shall include the following:

1) Reference to this American National Standard and the type of test procedure, Method A or Method B;

2) The type of hearing protector and its brand/product name, a copy of the exact instructions that accompanied the product and were used in the test protocol, any involvement of the requester's

representative at the time of test, and for Method A, any specific guidance from the requester for testing, additional training, or subject dismissal;

3) The number of subjects and any special selection criteria such as those relating to earcanal size or gender;

4) The number of hearing protector samples tested, and any samples that were rejected and the reason(s) why;

5) A table summarizing the mean real-ear attenuation at threshold values and the associated standard deviations rounded to integer values, as a function of the frequency of the one-third octave-band test signals, as well as the data for each trial on each individual subject;

6) A table of all subjects including those who were dismissed, specifying age and gender, and for tests of either earplugs or semi-inserts, the distribution of right and left earcanal sizes per Annex B, and for tests of semi-inserts, earmuffs, or helmets, the mean and standard deviation of the bitragion width and head height per Annex B;

7) In the case of hearing protectors with head or neck bands, the mean and standard deviation of the application force for all samples tested, the position (over head, under chin, or behind head) in which the force was tested, and the temperature and relative humidity at which the tests were conducted;

8) In the case of sized products, an indication of the sizes that were actually tested and how many subjects tested each size;

9) In the case of Method-B testing of earplugs provided with insertion assistance devices, the number of subjects who utilized those devices during earplug insertion;

10) A table of any subjects who were dismissed per Clause 8.2 of Method A, or Clauses 9.1 and 9.3.3 of Method B, specifying the reason(s) for each dismissal;

11) Discussion of any specialized requirements that were included in the test procedures, for instance, requiring subjects to wear personal protective equipment such as safety glasses during testing of earmuffs.

11.4 Graphical presentation of the data

When attenuation data are presented graphically, the frequency scale along the abscissa shall use equal intervals for each octave band, and the ordinate shall be linear in decibels. Attenuation shall be plotted so that it increases towards the bottom of the graph. A decade in frequency shall equal from 25 to 50 dB on the ordinate, which is equivalent to ratios of from 7.5 to 15 dB/octave.

Annex A

(informative)

Precision of real-ear attenuation measurements

[This annex is not part of ANSI/ASA S12.6-2008 *American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors* but is included for information purposes only.]

Sources of variability in the measurement of the attenuation of hearing protection devices are numerous. Determinations of occluded and unoccluded thresholds are affected by the subjects' ability to perform, willingness to participate and their attentiveness to the task. The fit of hearing protectors and the resulting attenuation is affected not only by the motivation of the subject and his or her training, but also by anatomical differences of each person's head or earcanal that affect the seal. These factors have the greatest effect on measured attenuation values; additional factors may be controlled through calibration and good laboratory practice. For instance, this standard specifies the linearity of the attenuators to ensure an accurate difference between the occluded and unoccluded conditions. The spatial and directional uniformity of the sound field are specified to minimize any effects from changes in the subject's head position. Background noise levels are specified to avoid the effects of masking for the unoccluded thresholds. This standard endeavors to minimize the effects of such acoustical and instrumentation differences as well as the degree of subject experience and subject/experimenter interaction to ensure consistency between different laboratories. In this annex, the variability or uncertainty at individual frequencies resulting from all of these factors is examined for different subject-training protocols, based on analyses of variance (ANOVA) of attenuation data from interlaboratory studies. This is followed by a discussion of how the uncertainty in overall attenuation performance (ratings) may be ascertained.

Data taken from several interlaboratory studies using procedures that differed in some respects from those in the current standard were analyzed to examine the underlying uncertainty (Royster *et al*. 1996; Murphy *et al*. 2004; Murphy *et al*. 2006). Figure A.1 illustrates the spread in attenuation measured for several different protectors using a naïve-subject-fit protocol similar to the Method B defined in the current standard, as reported by Murphy *et al*. (2004). Three important features are evident: the narrow unimodal distributions of the attenuations for the earmuff, the slightly wider but unimodal distributions for the foam earplug, and the even greater spread in the data and the bimodal nature of the distributions at low frequencies for the two premolded earplugs. The attenuation data were measured for nearly 100 subjects for the earmuff and EP100 earplug and for about 150 subjects for the Classic and V-51R earplugs. The spread in data expected from trained-subject-fit testing (Method A in this standard) should be more tightly distributed, so long as the experimenter/subject interaction is consistent across laboratories.

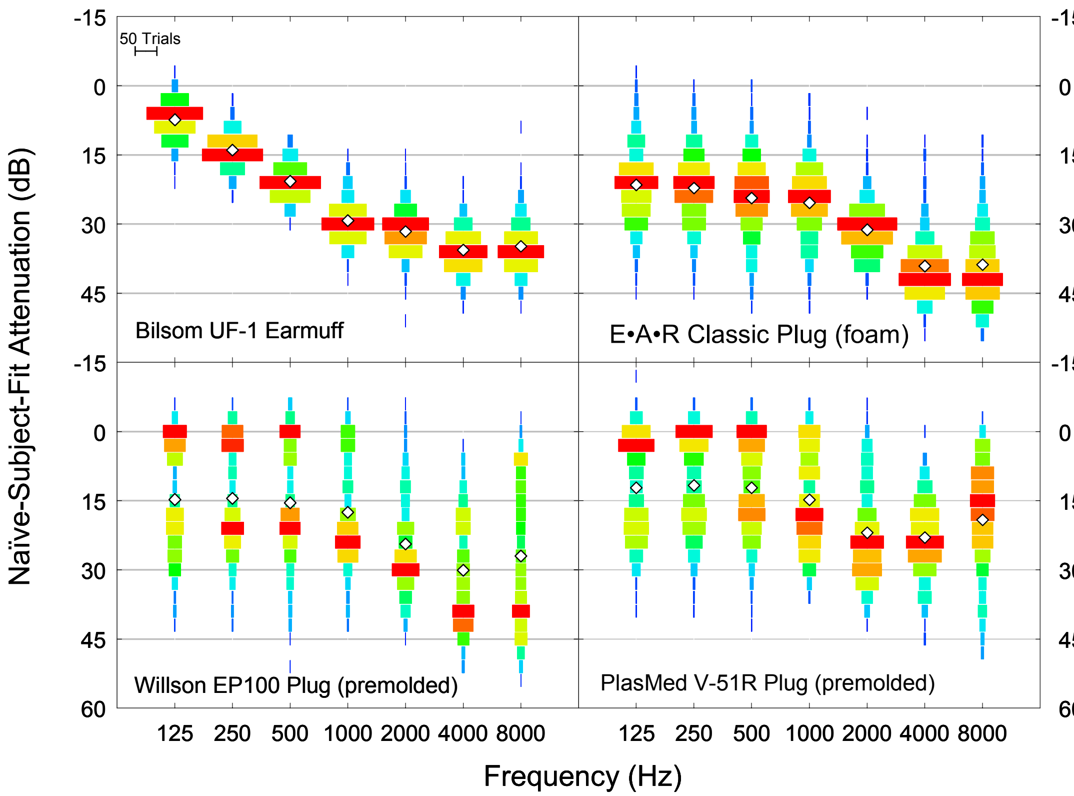

Figure A.1 — Histograms of naïve-subject-fit REATs for an earmuff, a foam earplug, and two premolded earplugs, pooling data from multiple laboratories. The width of the different colored bars denotes the number of trials in each attenuation bin; see the scale at upper left. The bimodal characteristics resulting from good and poor fitting by different naïve subjects are evident in the EP100 and V-51R distributions below 2000 Hz. (Used with permission, Murphy *et al*. 2004)

ANOVA of data for a single hearing protector model can provide insight into different aspects of the underlying uncertainty in attenuation. Repeatability is the expected performance when the device is re-tested under identical measurement conditions; in this case, the same facility, equipment and test subjects are used. Reproducibility can be defined in two ways: 1) testing a different group of subjects in the same facility and 2) testing a different group of subjects in a different facility. In this annex, the second definition is the focus.

In Royster *et al*. 1996 and Murphy *et al*. 2004, an ANOVA was performed on the naïve-subject-fit and experimenter-supervised-fit data to determine the standard deviations (σ_{trial} and σ_{subject}) of the attenuations for each frequency. Murphy *et al*. (2004) combined these terms to estimate the repeatability ($\sigma_{\text{between-subject}}$) as follows,

$$\sigma_{\text{between-subject}} = \sqrt{\frac{\sigma^2_{\text{subject}}}{n_s} + \frac{\sigma^2_{\text{trial}}}{(n_s n_t)}} \qquad \text{(A.1)}$$

where n_t and n_s are the number of trials and subjects, respectively. Including the laboratory variability, $\sigma_{\text{laboratory}}$, yields the reproducibility ($\sigma_{\text{between-laboratory}}$) as given in Equation A.2,

$$\sigma_{\text{between-laboratory}} = \sqrt{\sigma^2_{\text{laboratory}} + \frac{\sigma^2_{\text{subject}}}{n_s} + \frac{\sigma^2_{\text{trial}}}{(n_s n_t)}} \quad \text{(A.2)}$$

For the 2006 interlaboratory study, a similar ANOVA was performed on the attenuation data to estimate these standard deviations for trial, subject and laboratory effects. Repeatability and reproducibility were then determined for each test frequency according to the above equations. The ranges of repeatability for different product types are shown in Figure A.2 for the experimenter-supervised-fit data in the left panel and the naïve-subject-fit data in the right panel.[2] As might be expected, the repeatability estimates for earmuffs (dark gray) are smaller than those for earplugs (light gray). The repeatability estimates for earmuffs were similar for the two fitting protocols; however, the repeatability estimates for earplugs were slightly smaller on average for experimenter-supervised-fit than for naïve-subject-fit. Note also that the range of the repeatability across products was larger for earplugs than for earmuffs.

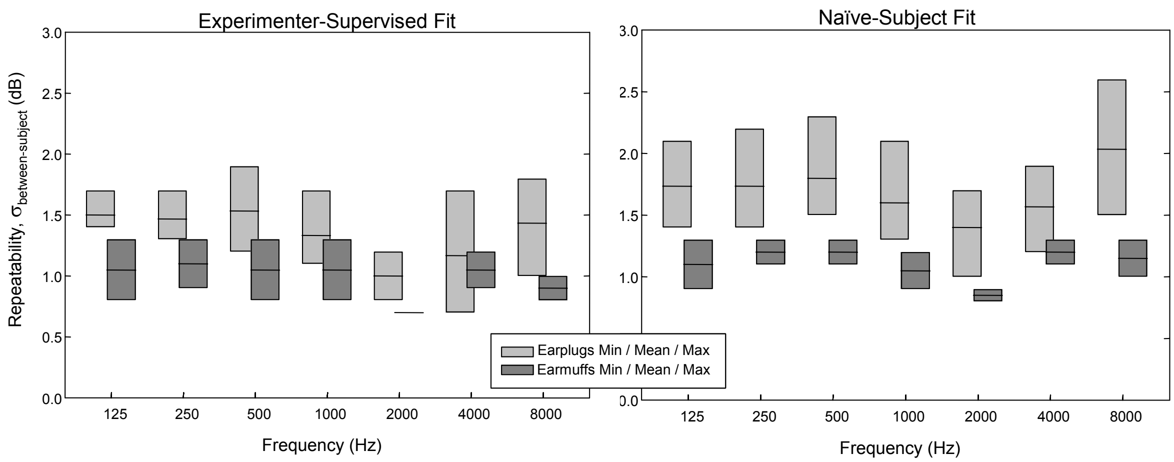

Figure A.2 — Repeatability for experimenter-supervised-fit and naïve-subject-fit protocols as estimated from the ANOVA of the REAT data from the 2006 interlaboratory study (Murphy *et al.*, 2006)

[2] The fitting protocols used in the 2006 study resulting in the variability depicted in Figures A.2 and A.3 differ substantially from the Method-A trained-subject-fit and slightly from the Method-B inexperienced-subject-fit protocols defined in this revision to the standard.

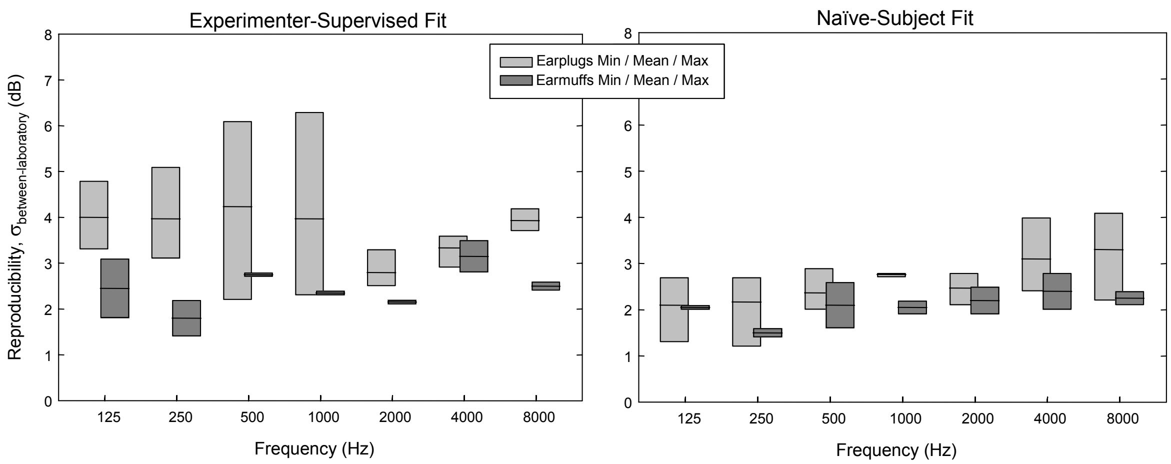

Figure A.3 — Reproducibility for experimenter-supervised-fit and naïve-subject-fit protocols as estimated from the ANOVA of the REAT data from the 2006 interlaboratory study (Murphy *et al*., 2006). Note the expanded scale compared to Figure A.2

In Figure A.3 the reproducibility is shown for each test frequency. It shows that the variability across laboratories for earplugs was much greater, at frequencies below 2000 Hz (where the effect of varying fit quality dominates; see Figure A.1), under experimenter-supervised fit as compared to naïve-subject fit. The reproducibility estimates for the earmuffs showed smaller variances and were comparable for the two fitting protocols. The large interlaboratory $\sigma_{\text{between-laboratory}}$ values seen in the experimenter-supervised fit data in this study is what motivated the changes in the revised Method A (trained-subject fit) protocol defined in this revision to the standard; it is expected that future studies will exhibit smaller variances in interlaboratory reproducibility, but possibly increased variance for within-laboratory repeatability than is shown in the above figures.

The above results address only the uncertainty at each test frequency, treating the data at different frequencies as independent, and are provided as guidance as to how much repeated tests in different laboratories may differ. To ascertain whether two given tests can be deemed significantly different in the statistical sense, one should compute the mean and standard deviation per Clause 11.2 of the standard and apply the Student's t-test. In some cases the non-normal character of the distribution of the attenuation data, such as the distributions at lower frequencies for the premolded plugs shown in Figure A.1, make this approach problematic. In such cases, the use of computational statistical methods (Bootstrap or Monte Carlo Methods) might be more appropriate to establish the confidence interval of such data (Efron and Tibshirani, 2003; Martinez and Martinez, 2005).

Of perhaps greater relevance is the uncertainty in the overall performance of a hearing protector such as is defined by Noise Reduction Rating (NRR: EPA, 1978), the Single Number Rating (SNR: ISO 4869-2) and the Noise Reduction Statistic for A-weighting (NRS_A: ANSI/ASA S12.68-2007). Murphy *et al*., (2004) suggested that the uncertainty in the overall performance of a hearing protection device is determined by the maximum standard deviation across the test frequencies. This, however, must be conditioned by the shape of the A-weighting response used in the rating definition, the average attenuation of the protector, and the noise spectra used to define the rating. For some ratings (NRR and SNR), these factors can be combined analytically to determine the overall performance uncertainty. For the NRS_A, Annex D of ANSI/ASA S12.68-2007 defines a computational statistics approach based on the Bootstrap method to determine the expanded uncertainty (half the width of the 95% confidence interval) from the REAT data used to compute the rating, as well as how to use this uncertainty to compare two tests for a significant difference.

An alternate method to estimating the expanded uncertainty associated with a REAT measurement may be found in recent ISO attenuation test standards (ISO/TS 4869-5:2006, Annex A) based on the *Guide to the expression of uncertainty in measurements* (GUM, 1993*)*. This approach estimates the overall variance as the square root of the sum of the related variance terms, with the dominant ones being due to subject thresholds in the open and occluded conditions, yielding similar results to those found here.

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Annex B

(normative)

Procedure for measuring earcanal sizes and head dimensions

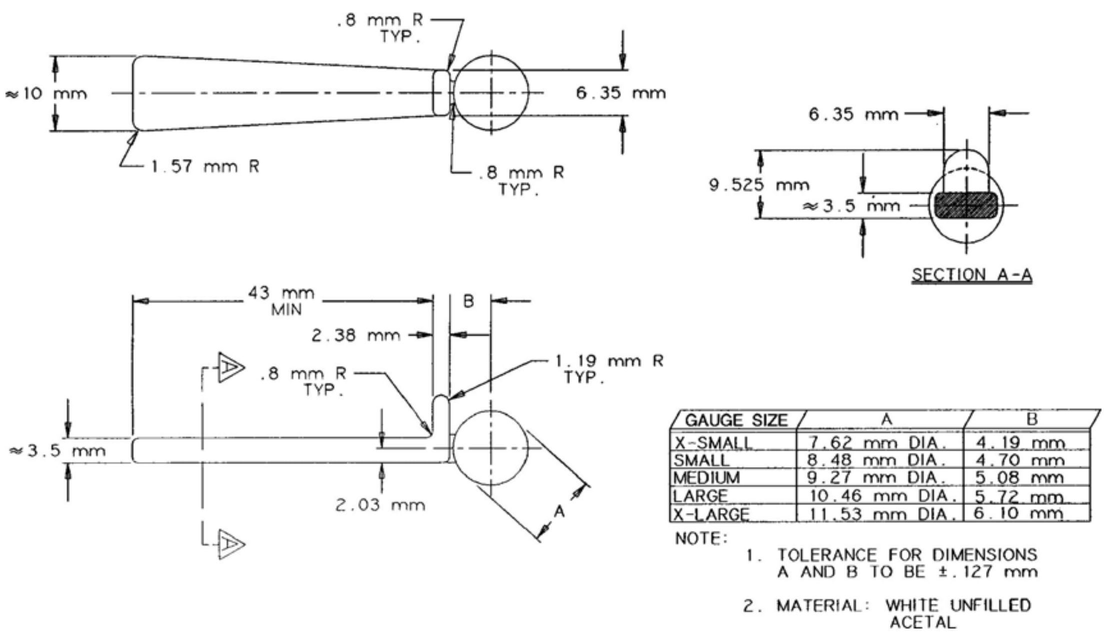
[This annex is a mandatory part of ANSI/ASA S12.6-2008 *American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors*.]

The device to be used for sizing earcanals is shown in Figure B.1. It consists of 5 plastic spheres denoted as extra small (XS), small (S), medium (M), large (L), and extra large (XL), with the dimensions listed in the table accompanying Figure B.1.

NOTE The laboratory may produce its own sizing device meeting the requirements shown in Fig. B.1 or may purchase a device. [3]

Choose a sphere that appears to be a little small for the earcanal being measured. Pull the pinna outward and upward to assist in placing the gauge in the earcanal opening until the tab of the gauge touches the floor of the concha. Release the pinna and observe if the entire earcanal opening conforms to the sphere. Then pump the gauge in the earcanal with a slight, gentle movement of about 1–2 mm. Ask the subject if s/he feels a suction or pressure. Move up in gauge size until the subject feels suction, the earcanal opening appears to conform to the sphere, *and* the gauge tab still lies on the concha floor, indicating a fully inserted sphere. The sphere accommodating these requirements represents the size of the earcanal.

If suction can only be achieved with a partial insertion, recheck the next smaller size to confirm. The assigned size will be the size that achieves suction.



GAUGE SIZE	A	B
X-SMALL	7.62 mm DIA.	4.19 mm
SMALL	8.48 mm DIA.	4.70 mm
MEDIUM	9.27 mm DIA.	5.08 mm
LARGE	10.46 mm DIA.	5.72 mm
X-LARGE	11.53 mm DIA.	6.10 mm

Figure B.1 — Dimensions of a tool to size earcanals

[3] Suitable units such as the EARGAGE™ Earplug Sizing Device are available from Aearo Technologies. Equivalent units from other sources may be used.

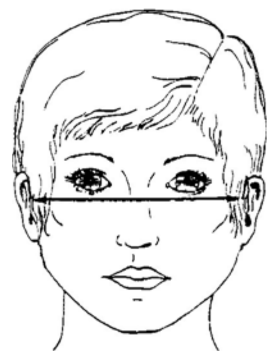


Figure B.2 — Bitragion width

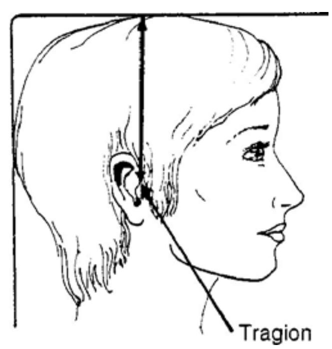


Figure B.3 — Head height

The head dimensions requiring measurement are bitragion width, which is the breadth of the head as measured from right to left tragion (commonly called head width), and head height, which is the distance from the tragion to the level of the top of the head, as illustrated in Figures B.2 and B.3. The tragion (see Figure B.3) is the superior point on the juncture of the tragus of the ear with the head, i.e., the notch just above the tragus. Bitragion width is normally measured with a caliper, and head height with a right angle and a straight edge.

Annex C

(informative)

Checklist for implementing Methods A and B

Initial interview and first visit

1) For Method B *only*, interview subject (S) prior to lab visit to verify acceptance per Clauses 9.1.1. and 9.1.2.

2) Explain study and go over informed consent (Clause 7.1).

3) Remove jewelry and glasses if necessary (Clause 5.7).

4) Conduct otoscopic exam (Clause 5.2).

5) Measure earcanal sizes and head dimensions (Clause 5.3; results to be withheld from subject).

6) Conduct screening audiogram (Clauses 5.5.1 and 5.5.2).

7) Conduct training with minimum of 5 open-ear sound-field audiograms (Clause 5.6).

Method A: Trained-subject fit

1) See Clauses 5.1 to 5.7 for S selection criteria and preparation. Also, S may be dismissed if a good fit cannot be obtained or if S cannot perform acceptably with respect to threshold audiometry (Clause 8.2).

2) **Outside chamber** (*no time limit*): help S size and fit; may give verbal and physical assistance and use fitting noise (Clause 8.1).

3) S removes HPD and **enters chamber** (Clause 8.1).

4) 2-min. quiet period before first threshold and waiting period after the HPD is fitted (see Clauses 7.6 and 7.7). The quiet period and waiting period may be observed simultaneously when the first threshold is an occluded one.

5) **Testing procedure** (*no time limit*): Begin with open-ear test or have S fit HPD using fitting noise, but with NO ASSISTANCE from experimenter (see Clause 8.3).

6) Subject is instructed to notify the experimenter of a change in fit of hearing protector during test (Clause 8.3, paragraph 2).

7) Measure open and occluded thresholds according to the counterbalancing in Clause 7.4.

Method B: Inexperienced-subject fit

1) See Clauses 5.1 to 5.7 for S selection criteria and preparation. S cannot be dismissed for any reasons pertaining to fit. Confirm S meets limitations on reuse in Clause 9.1.3.

2) **Outside chamber** (*10-min. time limit*): read verbatim text to S. Hand S the HPD in original packaging to size and practice fitting with NO ASSISTANCE and no fitting noise (see Clause

9.2.1). Set adjustable band force device per Clause 6.2. Observe applicable restrictions specified in Clauses 9.2.1.1 through 9.2.1.4.

3) S removes HPD and **enters chamber** (Clause 9.2.1).

4) 2-min. quiet period before first threshold and waiting period after the HPD is fitted (see Clauses 7.6, 7.7, and 9.2.1). The quiet period and waiting period may be observed simultaneously when the first threshold is an occluded one.

5) **Testing procedure** (*5-min. time limit for single hearing protector and 8-min. time limit with dual hearing protection*): Begin with occluded-ear test per 9.3.1 and read verbatim the specified text in Clause 9.3.1 to S. Leave chamber and turn on fitting noise (Clause 4.3.6), but without indicating to subject the purpose of the noise. S fits HPD. Experimenter provides NO ASSISTANCE. Alternatively, if an open-ear test is administered first, begin with Clause 9.3.2.

6) If HPD loses seal after testing begins, refer to Clause 9.3.3 for instructions, and also refer to that clause for guidance on conducting the second trial of open and occluded thresholds.

7) Measure open and occluded thresholds according to the counterbalancing in Clause 7.4.

NOTE This Annex provides abbreviated summary of the testing requirements of this standard. The entire standard should be read and studied to properly implement the required procedures.

Annex D

(normative)

Procedure for measurement of the band force of semi-insert devices

[This annex is a mandatory part of ANSI/ASA S12.6-2008 *American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors*.]

The band force for semi-inserts shall be measured with the pod separation equivalent to that observed on human heads of a median head width corresponding to that used for the earmuff measurements, namely, 145 mm. In this case the 145-mm dimension is measured as a bitragus breadth using the pinna and plastic base described below. Since semi-inserts rest in the concha and not on the circumaural regions, use of flexible pinnae are required, as described in Figure D.1 and Table D.1, both taken from page 4 of ANSI S3.36-1985. The pinna shall have a firmness that falls between a Shore A durometer reading of 10 and 30.

NOTE The laboratory may produce their own pinnae meeting the requirements shown in Figure D.1 and Table D.1, or may purchase a device.[4]

A suitable rigid plastic base in which to seat the pinna for use with typical band force measuring systems is shown in Figure D.2. Note that the base includes a centrally located recess to allow for penetration of semi-insert pods through the very shallow earcanal which is part of the flexible pinna.

Table D.1 — Pinna dimensions for force measurements of semi-insert devices, from Table II ANSI S3.36-1985

Ear length	66 mm
Ear length above tragion	30 mm
Ear breadth	37 mm
Ear protrusion	23 mm
Ear protrusion angle	160°
Vertical tilt, front view	10°
Vertical tilt, side view	6°
Concha length	28 mm
Concha length below tragion	20 mm
Concha breadth	23 mm
Concha breadth, tragion to helix	23 mm
Concha depth	15 mm

[4] Suitable units such as the KEMAR® pinnae Models KB0065 (left ear) and KB0066 (right ear) are available from G.R.A.S. Sound & Vibration. Equivalent units from other sources may be used.

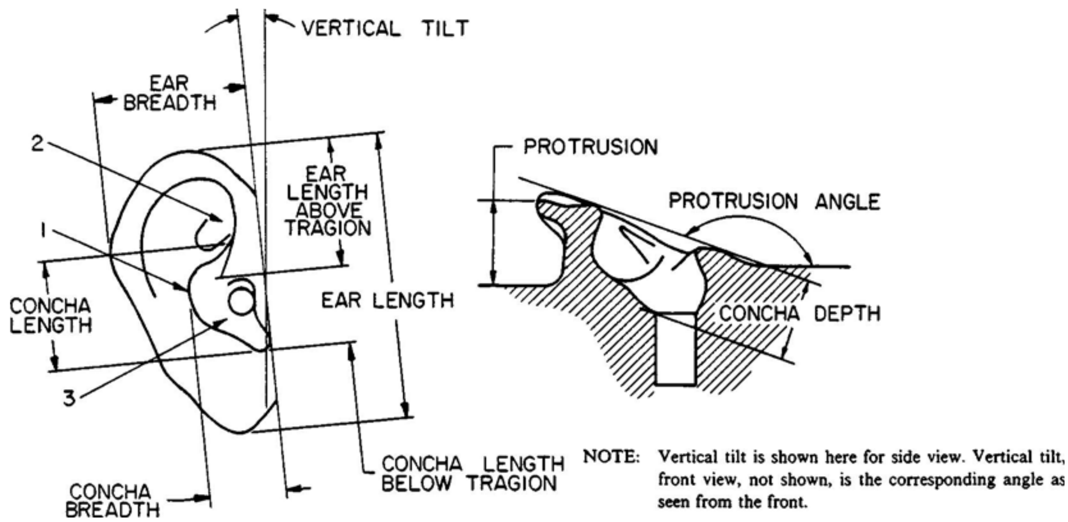
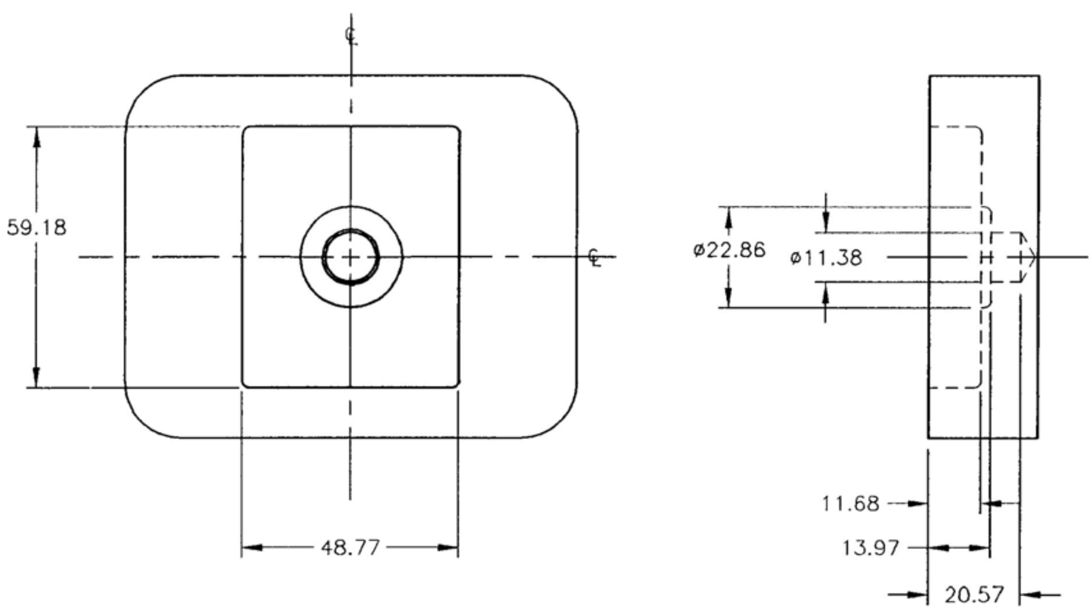


Figure D.1 — Definitions of semi-insert pinna adapter dimensions: (1) antihelix, (2) crus of helix, (3) concha



NOTES:

1. ALL DIMENSIONS IN MILLIMETERS
2. MATERIAL: POLYCARBONATE SHEET
3. BREAK ALL SHARP CORNERS AND EDGES
4. TOLERANCE TO BE ±.127 mm UNLESS OTHERWISE SPECIFIED

Figure D.2 — Rigid base plate suitable for pinna adapter

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