AMERICAN NATIONAL STANDARD

Methods for Measuring the Real-Ear Attenuation of Hearing Protectors

ANSI/ASA S12.6-2016

Accredited Standards Committee S12, Noise

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Methods for Measuring the Real-Ear Attenuation of Hearing Protectors

Secretariat:
Acoustical Society of America

Approved on June 16, 2016 by:
American National Standards Institute, Inc.

Abstract
This standard specifies laboratory-based procedures for measuring, analyzing, and reporting the passive noise-reducing capabilities of hearing protectors. 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 carefully trained users, and Method B) inexperienced-subject fit, utilizes subjects with little or no experience with respect to the use of hearing protection, in order to approximate the attenuation that can be attained by groups of users as reported in real-world occupational studies. 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 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 S12.6-2016 American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors* (revision of ANSI/ASA S12.6-2008). *As such, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the standard*.]

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/ASA S12.6-2008. The principal changes in this update pertain to the definition of the filters used in signal generation, room ambient noise requirements and various other items regarding the test site as described in Clause 4, retention of subjects during Method-B testing, a completely revised annex on the computation of uncertainty in close harmonization with the related specifications in ISO 4869-1, and inclusion of requirements on laboratory procedures for purposes of accreditation for laboratories choosing to become accredited.

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 ambient 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 use 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 S12.68-2008 (R2012). This standard also does not pertain to physical attenuation measurements using acoustical test fixtures or microphones mounted in human earcanals; those procedures are covered in ANSI/ASA S12.42-2010. And finally, with respect to attenuation obtained by individual users, a standard is under development that will provide specifications for field attenuation estimation systems (FAES) intended to estimate the personal attenuation ratings of hearing protection devices obtained by individual wearers in actual practice (BSR/ASA S12.71-201X).

At the time this standard was submitted to Accredited Standards Committee S12, Noise for approval, the membership was as follows:

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Working Group S12/WG 11, Hearing Protector Attenuation and Performance, which assisted Accredited Standards Committee S12, Noise, in the development of this standard, had the following membership.

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Suggestions for improvements of this standard will be welcomed. They should be sent to Accredited Standards Committee S12, Noise, in care of the Standards Secretariat of the Acoustical Society of America, 1305 Walt Whitman Road, Suite 300, Melville, New York 11747-4300. Telephone: 631-390-0215; Fax: 631-923-2875; E-mail: asastds@acousticalsociety.org.

Introduction

This standard describes real-ear attenuation at threshold (REAT) methods for the measurement of the noise attenuation of hearing protection devices (HPDs). Variations of this approach have been in wide use since the development of ASA Z24.22-1957. REAT data have generally been recognized as yielding the best measure of the noise attenuation provided by passive hearing protection devices and include the effects of sound transmission from flanking pathways, such as those arising from tissue and bone conduction (Berger, 1986).

Key factors influencing the measured attenuation values are the selection, training, and fitting of the hearing protector test subjects. For that reason this standard includes two methods with distinctly differing approaches for dealing with these issues.

Method A, 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. It allows full training and intervention by the experimenter prior to the attenuation measurement, 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 can be obtained in practice. The reason to preclude the experimenter from actually fitting the device was the observation that experimenters, who vary in the ways they interpret the standard and perform HPD fitting, can increase interlaboratory variability (Murphy *et al.*, 2009). To some extent, isolating the experimenters from the actual test reduces this problem. Furthermore, in actual use, whether trained or not, workers and others don hearing protectors without assistance.

Method B, previously called "subject fit" and currently designated "inexperienced-subject fit" to clearly indicate the key feature of the procedure, intends to approximate "achievable" results for *groups* of 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. 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 influenced by their preconceptions and acquired level of skill (Berger, 1992).

Method B was developed by the Working Group responsible for this standard by evaluating various protocols via both a pilot and an initial full-scale interlaboratory comparison study (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 incorporated into the current standard (Murphy *et al.* 2009).

Sincerely interested and/or highly motivated *individuals* may obtain workplace attenuation values significantly exceeding Method-B, and even potentially exceeding Method-A results, but for most populations of occupational users, the inexperienced-subject-fit estimates will provide better predictors of group average data than will the Method-A results. The validity of the estimates has been assessed by comparing laboratory-measured values arrived at using procedures similar to 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).

Method A yields higher mean attenuation values and lower within-test standard deviation values than Method B, with the effect being substantially larger for earplugs than for earmuffs because of the greater difficulty in fitting insert devices. See Annex A for information on estimating the uncertainty of these procedures.

American National Standard

Methods for Measuring the Real-Ear Attenuation of Hearing Protectors

1   Scope

1.1   Scope

This standard specifies laboratory-based subjective-method for measuring, analyzing, and reporting the passive noise-reducing capacity of hearing protection devices. The methods consist of psychophysical tests conducted on groups of 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 groups of 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 values are useful to estimate performance for individually trained and well-motivated 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 active hearing protection devices when the electronics are turned off. For evaluation of active hearing protection devices with their electronics turned on, see ANSI/ASA S12.42. 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 attenuation 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. To evaluate performance at peak SPLs greater than 140 dB guidance may be found in ANSI/ASA S12.42.

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/ASA S1.1, *American National Standard Acoustical Terminology*

ANSI/ASA S1.4-2014/Part 1/IEC 61672-1:2013, *American National Standard Electroacoustics – Sound Level Meters – Part 1: Specifications*

ANSI/ASA S1.11-2014/Part 1/IEC 61260-1:2014, *American National Standard Electroacoustics – Octave-band and Fractional-octave-band Filters – Part 1: Specifications*

ANSI/ASA S3.1-1999 (R2013), *American National Standard Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms*

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

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

ANSI/ASA S3.36-2012, *American National Standard Specification for a Manikin for Simulated in-situ Airborne Acoustic Measurements*

ANSI/ASA S12.68-2007 (R2012), *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/ASA S1.1, ANSI/ASA S3.20, and the following apply:

3.1   active hearing protection device. A hearing protection device that contains electronic components including transducers (i.e., speakers and microphones) to affect the transmission of sound into the earcanal.

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

3.3   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.

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

3.5   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.

3.6   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.

3.7   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.

3.8   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).

3.9   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.

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

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

3.12   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.

3.13   reference point. A fixed spatial location within the test chamber to which all of the objective measurements of the sound field characteristics are referenced and which coincides with the midpoint of a line connecting the test subjects' earcanal openings when the subject is seated for measurements.

3.14   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.

3.15 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).

3.16 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.

3.17 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 at all test frequencies measured with an omnidirectional microphone at six positions 15 cm from the reference point centered on the front-back, right-left and up-down axes shall deviate by no more than ± 2.5 dB from the sound pressure level at the reference point. Further, the difference between the right-left positions shall not exceed 3 dB. The orientation of the microphone shall be kept the same at each position and the subject and the subject's chair shall be absent.

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 figure-eight 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° 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° increments as the microphone is rotated 360° 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 shall be measured with an instrumentation system that meets the requirements of ANSI/ASA S1.4/Part 1/IEC 61672-1 class 1 and the filters shall meet the requirements of ANSI/ASA S1.11/Part 1/IEC 61260-1 type 1. The measured noise at the reference point, with the subject absent and with all signal presentation equipment on, shall not exceed the octave-band levels in Table 2. For systems with analog attenuators adjust the gain to 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. For systems with digital attenuation set the gain to the minimum value with the signal activated. Ambient noise levels shall be measured at least monthly during normal testing times, or more often if the laboratory conditions warrant. All ventilation, lighting and any other equipment in the vicinity that produces noise in the test facility shall be set as would be normal during threshold testing.

NOTE   The maximum permissible noise levels in Table 2 are predicated upon a listener with hearing thresholds no better than 0 dB hearing level. If the laboratory wishes to utilize listeners with better hearing, then ambient noise levels shall be reduced commensurately; i.e., if hearing levels are -10 dB at one or more frequencies, the noise levels shall also be reduced by 10 dB at those frequencies. Also see 5.5.2.

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.

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.

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/ASA 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.

4.3.1   Test signal (one-third 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/ASA S1.11/Part 1/IEC 61260-1, Class 1. 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 one-third octave-band test signals at the reference point, at sound pressure levels that comply with the maximum levels specified in 4.3.2, the one-third octave-band sound pressure levels shall be at least 40 dB down from the maximum level in octave bands from one octave below the test band down to 31.5 Hz, and from one octave above the test band up to 16 kHz. During the test, the sounds shall be reproduced without audible buzzing, crackle, or rattle.

4.3.4   Attenuator range and system linearity

Attenuators shall have a range of at least 90 dB for each test signal, and shall be evaluated for linearity with a step size of ≤ 3 dB.

The difference in output between any two attenuator settings, measured at a single one-third octave-band test signal (4.1), shall not differ from the indicated difference by more than 2 dB over the total attenuator range and not more than 1 dB over any 80-dB range. 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 with a signal reproduced from all channels simultaneously so that the linearity can be measured under conditions approximating that of the actual test and so as to include all parts of the measurement system that are potentially nonlinear. When the ratio of the acoustically measured sound pressure level to the ambient noise is less than 20 dB, which may occur for the lowest level test signals, the linearity of the signal voltage shall be measured at the terminals of the loudspeaker(s) using either pure-tone or one-third octave-band test signals.

To assure the frequency response of the system remains constant over its dynamic range, the standard one-third octave test bands (4.1) or a pink noise signal from 80 Hz to 10 kHz shall be used as a test stimulus to evaluate the usable range of the system in 10-dB decrements from the maximum levels the system can reproduce down to the ambient noise floor. The family of frequency response curves thus generated shall demonstrate no departures from linearity of greater than 2 dB for any of the one-third octave-band test frequencies.

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 position reference device

A head position reference 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 be small enough to not measurably affect the uniformity of the sound field of the room as specified in 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 specifically designated by the requester, the ratio of male to female subjects shall be between and including 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/ASA S3.6).

5.5.2 Maximum sound-field sensitivity relative to room ambient noise

No subject shall be used whose one-third 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 and method of selection 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. A test panel shall not be constructed based on attenuation results from prior testing.

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 use 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 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 (5 samples for attenuation testing and 1 sample for force testing).

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

For active hearing protection devices that couple to the ear with an earplug tip, the sample requirements for the tips shall be the same as in paragraph 1 of this clause. Additionally, there shall be a minimum of one of the active hearing protection devices for every four subjects. For active hearing protection devices that are in the form of earmuffs, the sample requirements shall be the same as in paragraphs 2 or 3 of this clause, as appropriate.

6.2 Earplugs connected via a flexible retaining cord

When earplugs are produced in both corded and uncorded versions and the manufacturer wishes to have a single set of attenuation data that apply to both versions, a sufficient number of samples of each version shall be provided such that one-half of the subjects test the corded product and one-half test the uncorded product.

6.3   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 8.1 or 9.2.

6.4   Special requirements for inexperienced-subject-fit method

Products shall include complete on-package and/or in-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.

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 (4.4), his or her head will be placed and maintained at the reference point (3.13) 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 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 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 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   Threshold sensitivity at time of testing

On the day of the testing the first open threshold audiogram shall be compared to the average of the last three of the subject's qualifying sound-field audiograms that were recorded per 5.6 and the values shall agree within 8 dB at each test frequency.

7.6   Open threshold variability within a test session

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.

7.7   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.

7.8   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. For devices that provide variable band force, the requester shall provide guidance on what force setting is to be used. 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 used (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 (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 repeatedly fail the requirements of 7.6, 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 while the HPD is being fitted and 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 7.7 and the waiting period specified in 7.8, 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 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 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 7.6. 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, or custom earplugs.

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 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 (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. <u>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. You will not be allowed to take the instructions with you into the test chamber."</u>*

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 used 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 otoblock, 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 otoblocks 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 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 7.7 and 7.8.

9.3.2 Beginning the testing (open threshold first)

The procedure is the same as in 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 7.7). Once the open threshold is completed, the experimenter returns and follows the instructions as in 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 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 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 underside 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 of contact with the test fixture 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.

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 bitragion width 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:

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

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

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

helmets). $N - 1$ is used for purposes of computing an unbiased estimate of the population standard deviation.

11.3 Estimation of the uncertainty and procedures for assuring laboratory conformity

The measurement of REAT has inherent uncertainties associated with various sources due to instrumentation and measurement issues, but most importantly due to issues involving the subject and the fitting of the HPD. Annex A provides a method to estimate the uncertainties associated with testing according to the requirements of this standard. In addition Annex E, which is normative only for laboratories that choose to apply for accreditation, is included to describe testing and procedures to assure laboratory conformity to this standard, and for purposes of laboratory accreditation.

11.4 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 used those devices during earplug insertion;

10) A table of any subjects who were dismissed per 8.2 of Method A, or 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.

11.5 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)

Uncertainty of hearing protector attenuation measurements

[This annex is not part of ANSI/ASA S12.6-2016 *American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors* but is included for information purposes only.]

A.1 General

Uncertainties in the measurement of the mean attenuation of a hearing protector according to this standard arise from various sources such as selection of the test subject group, fitting of the hearing protector on the test subjects, threshold determination by the test subjects, variation in the tester and administration of the test protocol, influence from the sound field, ambient noise and test equipment, etc.

The model, including uncertainties, for the calculation of the attenuation, A, for the test signals specified in this standard is

$$A = A_{REAT} + \delta_{meth} + \delta_{eq} + \delta_{env} \qquad (A.1)$$

where,

A_{REAT} is the outcome of a real-ear attenuation measurement according to this standard.

δ_{meth} is the input quantity to allow for the variation due to the selection of test subject group, fitting of the hearing protector, the variability of the subject's threshold determination, variation in tester and administration of protocol, and specimen variability.

δ_{eq} is the input quantity to allow for any deviation in the performance of the test signal generation equipment.

δ_{env} is the input quantity to allow for influence from non-ideal or varying environmental conditions, such as sound field and ambient noise.

A probability density function is associated with each source of uncertainty. The best estimate of each source is the mean value. The mean values of the δ-terms in Equation A.1 are assumed to be zero, and thus A_{REAT} is the best estimate of A. The standard deviation of each source, i, is an estimate of the standard uncertainty, u_i, associated with that source.

The combined uncertainty, u, depends on the standard uncertainties, u_i, from all sources and their sensitivity coefficients, c_i. The sensitivity coefficient is a measure of how the value of attenuation is affected by the change in its respective input quantity. The combined standard uncertainty is given by the square root of the sum of the squares of the separate standard uncertainties weighted by the sensitivity coefficients (Equation A.2).

$$u = \sqrt{\sum_i (c_i u_i)^2} \qquad (A.2)$$

In the model (Equation A.1), all of the probability distributions for the standard uncertainties, u_i, are assumed to be normal and all sensitivity coefficients, c_i, have a value of 1.

The data for the uncertainty of the experimental method is drawn primarily from Murphy et al. (2009), with reference also to ISO 4869 and supplemented by empirical knowledge.

Table A.1 illustrates the general estimation of the input quantities for δ_{meth}, δ_{eq}, and δ_{env}. The value of the standard uncertainty, u_{meth}, associated with input quantity, δ_{meth}, is frequency dependent. In Tables A.2 and Table A.4, u_{meth} is specified separately for test signals in three frequency ranges. The uncertainty value, u_{meth} is greater between laboratories than within laboratories, and generally greater for earplugs than for earmuffs. The values of u_{eq} and u_{env} are assumed to be independent of frequency.

The standard uncertainty values supplied in this Annex are considered representative of the measurements and equipment that would normally be used in Method-A hearing protector testing. No estimates for Method-B uncertainty budgets are provided at this time since the probability distributions for such testing often exhibit non-normal characteristics.

Table A.1 – General form of an uncertainty budget for hearing protector determinations

Source	Mean estimate dB	Standard uncertainty u_i dB	Probability distribution	Sensitivity coefficient c_i	Uncertainty contribution $u_i \cdot c_i$ dB
δ_{meth}	0	u_{meth}	Normal	1	u_{meth}
δ_{eq}	0	u_{eq}	Normal	1	u_{eq}
δ_{env}	0	u_{env}	Normal	1	u_{env}

The expanded uncertainty, U_{95}, is computed by multiplying the combined standard uncertainty, u, by a coverage factor k = 2 (appropriate for normally distributed parameters), such that an interval from A - U_{95} to A + U_{95} covers 95% of the values of A.

The following is a representative determination of uncertainty for the measurement of HPD attenuation, divided into two parts. One is about the uncertainty of measurements within a laboratory and the other relates to the uncertainty of measurements at different laboratories. The terminology and discussion are based on the guidance in JCGM 100:2008.

A.2 Uncertainty within a laboratory

The combined uncertainty, u, within a laboratory is the standard deviation of the mean attenuation. This is estimated from a calculation of the standard deviation of the individual attenuations divided by the square root of the number of test subjects, i.e., $\geq$ 10 subjects for earmuffs and $\geq$ 20 subjects for earplugs.

From the investigations referenced in A.1, typical uncertainty values may be given. Table A.2 shows the estimated uncertainty contributions within a laboratory for earplugs and earmuffs and for different frequency ranges. It also shows the combined and expanded uncertainties.

Table A.2 – Estimates of Method-A within-laboratory uncertainty for the mean attenuation

Component	Uncertainty contribution dB		
	< 250 Hz	250 Hz up to 4 kHz	> 4 kHz
u_{meth} – the uncertainty of the mean of individual attenuations of 20 test subjects (earplugs) or 10 (earmuffs) - earplug - earmuff	 1.4 1.0	 0.9 0.6	 1.2 1.0
u_{eq} – the uncertainty of test signal generation equipment	0.2	0.2	0.2
u_{env} – the uncertainty of deviations from ideal test environment	0.5	0.5	0.5
Combined standard uncertainty u - for an earplug - for an earmuff	 1.5 1.1	 1.1 0.8	 1.3 1.1
Expanded uncertainty U_{95} - for an earplug - for an earmuff	 3.0 2.2	 2.1 1.6	 2.6 2.2

For a specific set of measurements at a specific test site, and for a specific hearing protector, the combined uncertainty can be calculated from the individuals' attenuation values. This is shown in the example given in A.2.2.

A.2.1 Application of the expanded uncertainty

As an example of the application of the uncertainty values in Table A.2, consider a comparison of two attenuation measurements. The measurements are made for two different earplugs within a given laboratory on two occasions. The question is: Are the two results significantly different?

The two attenuation values cannot be deemed statistically significantly different if the means differ by less than twice the expanded uncertainty divided by the square root of two. In order for the difference to be considered significant, the necessary minimum difference is given by expression (A.3)

$$\text{minimum difference: } 2 \times U_{95} / \sqrt{2} = \sqrt{2} \times U_{95} \qquad \text{(A.3)}$$

From Table A.2 the expanded uncertainty for an earplug in the frequency range 250 Hz to 4 kHz is 2.1 dB. The minimum difference is thus $\sqrt{2} \times 2.1 = 3.0$ dB (rounded to one decimal). Therefore, two test values would have to differ by more than 3.0 dB in this frequency range in order for them to be considered significantly different at a confidence level of 95%.

For an earmuff the minimum difference will be 2.3 dB in the frequency range 250 Hz to 4 kHz.

A.2.2 An example

Table A.3 shows an example of earmuff data from a specific laboratory measured in accordance with this standard. The combined standard uncertainty is computed in that table as the experimental standard deviation of the mean, also referred to as the standard error of the mean. Note that this value may be calculated from the attenuation data from a specific laboratory.

Table A.3 – An example of Method-A earmuff test data in decibels for a given laboratory

Test subject	Frequency in Hz						
	125	250	500	1000	2000	4000	8000
1	17	25	22	37	31	36	37
2	24	20	24	32	34	38	37
3	14	25	31	35	30	38	39
4	20	23	31	37	34	41	42
5	13	27	32	36	34	42	37
6	16	22	30	30	34	37	38
7	13	19	31	35	37	42	38
8	17	24	36	37	35	38	43
9	13	16	28	35	36	38	34
10	16	21	28	33	31	38	37
Mean	14.7	20.0	29.7	34.1	33.3	36.5	37.2
Standard deviation (s)	3.4	4.4	4.7	4.3	2.7	5.3	4.5
Combined standard uncertainty, u, ($s/\sqrt{N}$)	1.1	1.4	1.5	1.4	0.9	1.7	1.4
Expanded uncertainty, U_{95}	2.2	2.8	3.0	2.7	1.7	3.3	2.8
NOTE: The data in each row for each subject represent the average of two trials conducted on that subject.							

A.3 Uncertainties between laboratories

From the investigations referenced in A.1, typical uncertainty values may be given. Table A.4 shows the estimated uncertainty contributions between laboratories for earplugs and earmuffs and for different frequency ranges. It also shows the combined and expanded uncertainties.

Table A.4 – Estimates of Method-A between-laboratory uncertainty for the mean attenuation

Component	Uncertainty contribution dB		
	< 250 Hz	250 Hz up to 4 kHz	> 4 kHz
u_{meth} – the uncertainty of the mean of individual attenuations of 20 test subjects (earplugs) or 10 (earmuffs) - earplug - earmuff	 3.9 1.7	 3.1 2.2	 3.1 3.0
u_{eq} – the uncertainty of test signal generation equipment	0.3	0.3	0.3
u_{env} – the uncertainty of deviations from ideal test environment	0.8	0.8	0.8
Combined standard uncertainty u - for an earplug - for an earmuff	 4.0 1.9	 3.2 2.4	 3.2 3.1
Expanded uncertainty U_{95} - for an earplug - for an earmuff	 8.0 3.8	 6.4 4.8	 6.4 6.2

A.3.1 Application of the expanded uncertainty

As an example of the application of the uncertainty values in Table A.4, consider a comparison of two attenuation measurements. The two measurements are made for the same type of earplug at two different laboratories. The question is: Are the two results significantly different?

The two attenuation values cannot be deemed statistically significantly different if the means differ by less than twice the expanded uncertainty divided by the square root of two. In order for the difference to be considered significant, the necessary minimum difference is given by expression (A.4)

$$\text{minimum difference: } 2 \times U_{95} / \sqrt{2} = \sqrt{2} \times U_{95} \tag{A.4}$$

From Table A.4 the expanded uncertainty for an earplug in the frequency range 250 Hz to 4 kHz is 6.4 dB. The minimum difference is thus $\sqrt{2} \times 6.4 = 9.1$ dB (rounded to one decimal). Therefore, two test values would have to differ by more than 9.1 dB in this frequency range in order for them to be considered significantly different at a confidence level of 95%.

For an earmuff the minimum difference will be 6.8 dB in the frequency range 250 Hz to 4 kHz.

Annex B

(normative)

Procedure for measuring earcanal sizes and head dimensions

[This annex is a mandatory part of ANSI/ASA S12.6-2016 *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. [2]

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

NOTE:
1. TOLERANCE FOR DIMENSIONS A AND B TO BE ±.127 mm
2. MATERIAL: WHITE UNFILLED ACETAL
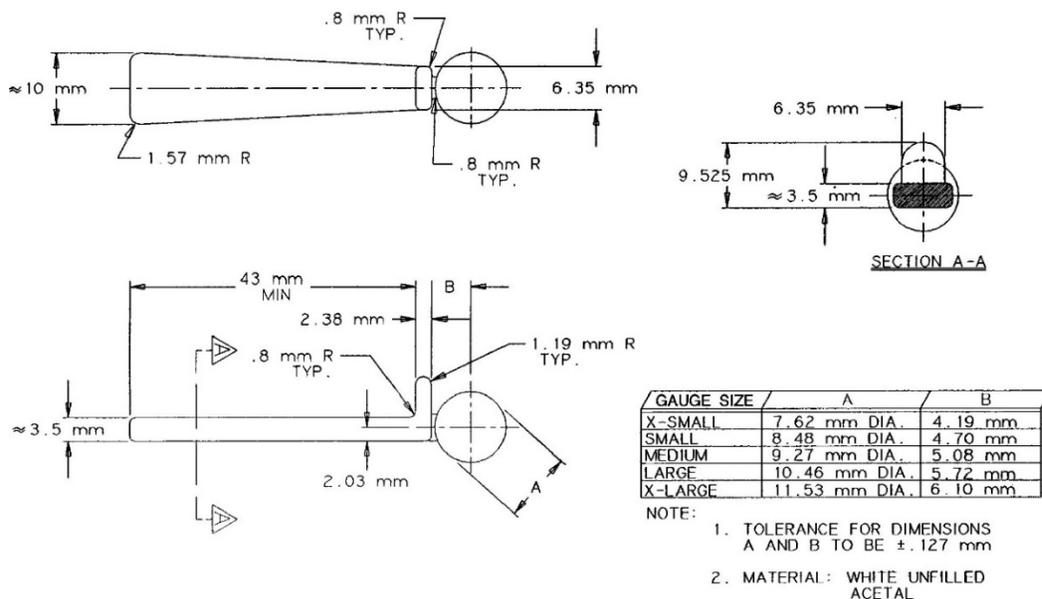
Figure B.1 — Dimensions of a tool to size earcanals

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[2] Suitable units such as the 3M™ Eargage Earcanal Sizing Tool are available. Equivalent units from other sources may be used.
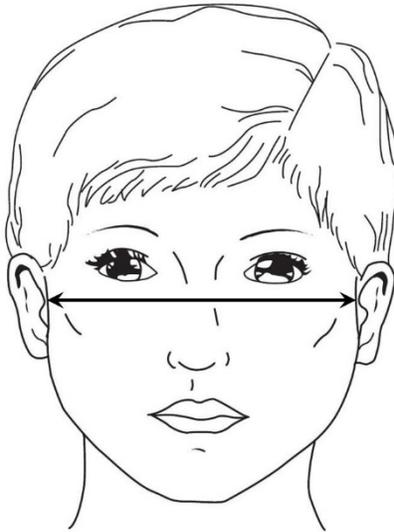
Figure B.2 — Bitragion width
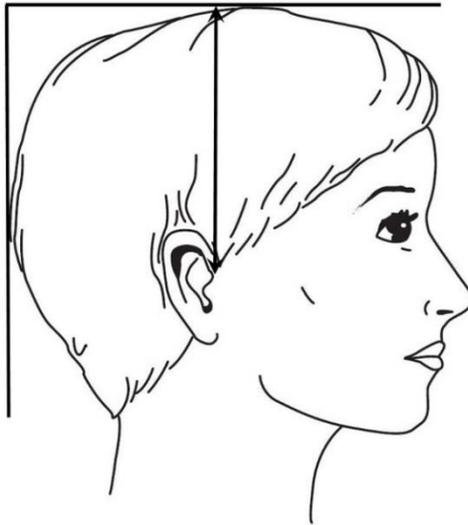
Figure B.3 — Head height

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 (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

[This annex is not part of ANSI/ASA S12.6-2016 *American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors* but is included for information purposes only.]

Initial interview and first visit

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

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

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

4) Conduct otoscopic exam (5.2).

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

6) Conduct screening audiogram (5.5.1 and 5.5.2).

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

Method A: Trained-subject fit

1) See 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 (8.2).

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

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

4) 2-min. quiet period before first threshold and waiting period after the HPD is fitted (7.7 and 7.8). 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 (8.3).

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

7) Measure open and occluded thresholds according to the counterbalancing in 7.3.

8) Verify subject threshold sensitivity and variability meets threshold requirements of 7.5 and 7.6.

Method B: Inexperienced-subject fit

1) See 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 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 (9.2.1). Set adjustable band force device per 6.2. Observe applicable restrictions specified in 9.2.1.1 through 9.2.1.4.

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

4) 2-min. quiet period before first threshold and waiting period after the HPD is fitted (7.7, 7.8, 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 9.3.1 to S. Leave chamber and turn on fitting noise (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 9.3.2.

6) If HPD loses seal after testing begins, refer to 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 7.3

8) Verify subject threshold sensitivity and variability meets threshold requirements of 7.5 and 7.6.

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 S12.6-2016 *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 bitragion width 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/ASA S3.36-2012. The pinna shall have a firmness that falls between a Shore 00 durometer reading of 30 and 60.

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.[3]

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 ANSI/ASA S3.36-2012, Table D.1

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

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[3] 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.
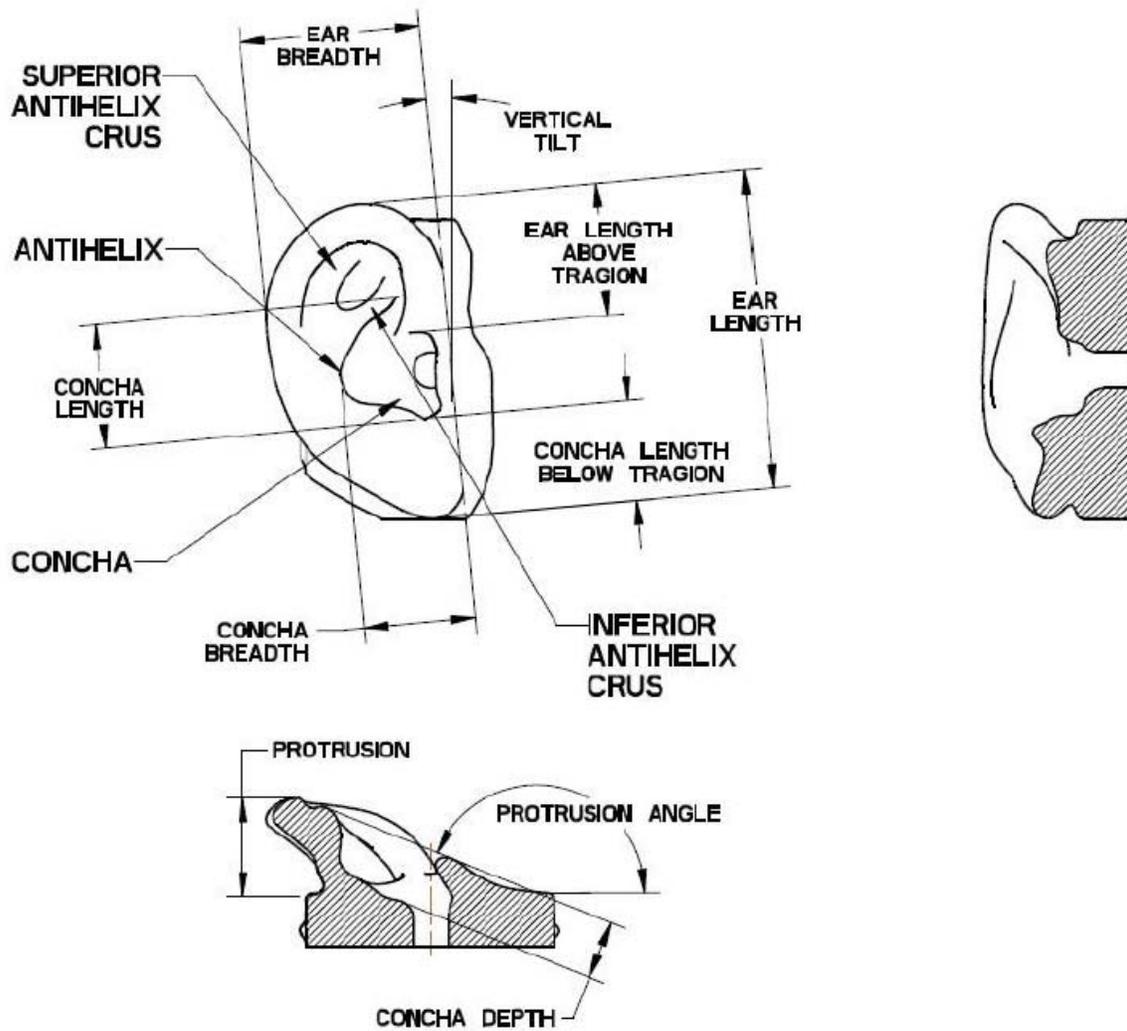
Figure D.1 — Semi-insert pinna adapter dimension definitions
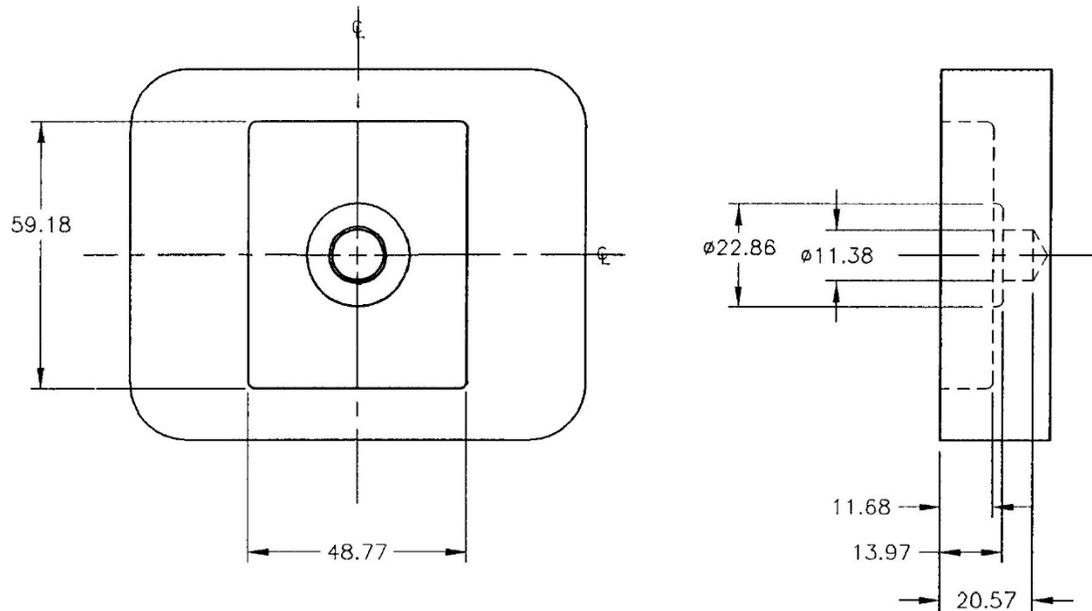
NOTES:

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

Annex E

(normative if accreditation is sought)

Requirements for accreditation

[This annex is a mandatory part of ANSI/ASA S12.6-2016 *American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors* for laboratories seeking accreditation, but is included for information purposes only for those not seeking accreditation.]

This annex describes the minimum information that shall be supplied by a laboratory to an accrediting authority and the procedures required to demonstrate compliance with all the provisions of this standard. Accrediting authorities are free to add to this set of requirements. The information required from the laboratory needs to be interpreted by a knowledgeable assessor. It is the responsibility of the accrediting agency to employ such individuals.

Laboratory Information

- The laboratory shall provide a layout drawing of the test facility showing the speaker locations, subject location, and key dimensions.

Instrumentation

- The laboratory shall provide documentation that the sound level measurement system used to qualify the facility and conduct the system validation testing, including the microphone, except for the directional microphone used in 4.2.1.2, meets the requirements of ANSI/ASA S1.4/Part 1/IEC 61672-1 for sound level meters.
- The laboratory shall provide documentation that the proportional octave-band filters used to qualify the facility and conduct the system validation testing meets the requirements of ANSI/ASA S1.11/Part 1/IEC 61260-1.

Facility Qualification

- The laboratory shall provide documentation of the sound field uniformity conducted in accordance with 4.2.1.1. Tests shall be conducted upon commissioning of the facility, when any significant changes to the sound field or sound system are made, or at least every 2 years.
- The laboratory shall provide documentation of the sound field directionality conducted in accordance with 4.2.1.2. Tests shall be conducted upon commissioning of the facility, when any significant changes to the sound field or sound system are made, or at least every 2 years.
- The laboratory shall provide documentation of the reverberation time conducted in accordance with 4.2.2. Tests shall be conducted upon commissioning of the facility, when any significant changes to the sound field are made, or at least every 4 years.
- The laboratory shall provide documentation of the ambient noise in the facility, conducted in accordance with 4.2.3. Tests shall be conducted upon commissioning of the facility, when any significant changes to host site or environmental control systems are made, or at least monthly.

Signal Generation and Threshold Detection

- The laboratory shall describe the type of signal being used as outlined in 4.1.
- The laboratory shall provide a signal generation system diagram showing all of the key system components outlined in 4.3.
- The laboratory shall provide documentation that the bandwidth of the test signal complies with the requirements outlined in 4.3.1. Tests shall be conducted upon commissioning of the system, when any significant change to the signal generation hardware or software is made, or at least every 2 years.

- The laboratory shall provide documentation that the test system complies with the dynamic range requirements outlined in 4.3.2. Tests shall be conducted upon commissioning of the system, when any significant change to the signal generation hardware or software is made, or at least every 2 years.
- The laboratory shall provide documentation that the test system complies with the distortion requirements outlined in 4.3.3. Tests shall be conducted upon commissioning of the system, when any significant change to the signal generation hardware or software is made, or at least every 2 years.
- The laboratory shall provide documentation that the test system complies with the attenuator linearity requirements outlined in 4.3.4. Tests shall be conducted upon commissioning of the system, when any significant change to the signal generation hardware or software is made, or at least every 2 years.
- The laboratory shall provide documentation that the test system complies with the signal pulsing requirements outlined in 4.3.5. Tests shall be conducted upon commissioning of the system, when any significant change to the signal generation hardware or software is made, or at least every 4 years.
- The laboratory shall provide documentation that the threshold determination method of the system complies with the requirements of 7.4 and documentation of all key parameters used by the threshold seeking algorithm and shall demonstrate that thresholds are computed correctly.

Subject Selection and Information

- The laboratory shall document its general procedures for subject selection for each method of testing (Method A and/or Method B) conducted.
- The laboratory shall document its procedures for conducting otoscopic inspections and anatomical measurements as outlined in 5.1 and 5.2.
- The laboratory shall document its procedures for determining subject hearing sensitivity qualification as outlined in 5.5.
- The laboratory shall document its procedures for determining subject threshold variability as outlined in 5.6.
- The laboratory shall provide documentation of its procedures for informing subjects for each method of testing (Method A and/or Method B) conducted.

Test Procedures

- The laboratory shall provide a copy of the written work instructions followed by the test operator during a test.
- The laboratory shall provide a copy of its written work instructions for head band force measurement, if applicable.
- The laboratory shall provide a test demonstration, conducted in accordance with the laboratory work instructions, which the accrediting agency assessor shall both experience as an unqualified test subject and witness during testing. Assessment shall include listening for extraneous noises and signal fidelity.

Test Reports

- The laboratory shall provide the accrediting agency a copy of its standard test report format for the test method that meets the requirements of 11.4 and 11.5.
- The accrediting agency should select several past test reports issued by the laboratory and audit them for compliance with 11.4 and 11.5 and audit the test data obtained as part of the tests.

Estimation of Uncertainty

- The laboratory shall maintain reference earplug and earmuff test specimens to be used for repeatability testing. However if the lab does not test insert products an earplug specimen need not be retained and if the lab does not test circumaural products, an earmuff specimen need not be retained.
- The laboratory shall conduct repeatability testing on its reference specimen(s) at least every 2 years.

- The laboratory shall provide a control chart analyzing the repeatability data and comparing the results to the within-laboratory uncertainty values provided in Annex A.
- Repeatability data that fall outside of the guidance provided by Annex A shall be investigated and provided to the accrediting agency with technical explanation.

Bibliography

[1]   ANSI/ASA S12.42-2010, *American National Standard Methods for the Measurement of Insertion Loss of Hearing Protection Devices in Continuous or Impulsive Noise Using Microphone-in-Real-Ear or Acoustic Test Fixture Procedures.* Acoustical Society of America, New York, 2010.

[2]   BSR/ASA S12.71-201x (draft), P*erformance Criteria for Systems Designed to Estimate the Attenuation Obtained by Individual Users of Passive Hearing Protectors*. Acoustical Society of America, New York, 2014.

[3]   ASA Z24.22-1957 (R1971), *American National Standard Method for the Measurement of the Real-Ear Attenuation of Ear Protectors at Threshold*. Acoustical Society of America, New York, 1957 (NOTE: This standard was approved as a USA Standard. It became an American National Standard in October 1969 when the Institute changed its name to American National Standards Institute, Inc.).

[4]   Berger, E. H. (1986). "Review and Tutorial - Methods of Measuring the Attenuation of Hearing Protection Devices," *J. Acoust. Soc. Am.* 79(6), 1655–1687.

[5]   Berger, E. H. (1992). "Development of a Laboratory Procedure for Estimation of the Field Performance of Hearing Protectors," in Proceedings, Hearing Conservation Conference, Off. Eng. Serv., Univ. Kentucky, Lexington, KY, 41–45.

[6]   Berger, E. H., Franks, J. R., and Lindgren, F. (1996). "International Review of Field Studies of Hearing Protector Attenuation," in Scientific Basis of Noise-Induced Hearing Loss, edited by A. Axelsson, H. Borchgrevink, R. P. Hamernik, P. Hellstrom, D. Henderson, and R. J. Salvi, Thieme Med. Publ., Inc., New York, NY, 361–377.

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