The Insertion Loss Distribution Function of An Ear Plug, and Its Implications for the Ear Plug Acceptability

Paolo Lenzuni, Diego Annesi, Pietro Nataletti
Italian National Workers’ Compensation Authority (INAIL)

Abstract

Introduction: In order to establish the acceptability of a hearing protector device (HPD) used in a given noisy environment, two key elements must be known with the highest possible accuracy: the insertion loss of the HPD and the associated variability. Methods leading to objective field measurements of insertion loss have become widely available in the last decade and have started to replace the traditional subjective “Real-Ear Attenuation at Threshold” (REAT) laboratory measurements. The latter have long been known to provide a gross overestimate of the attenuation, thus leading to a strong underestimate of the worker’s exposure to noise. Methods: In this work we present objective measurements of the insertion loss of an ear plug, carried out using the E-A-Rfit procedure by 3M on a large sample of 36 female and 64 male subjects. This large number of independent measurements has been exploited to calculate the distribution function of effective noise levels, that is noise levels that take into account the use of the HPD. The knowledge of the distribution function has in its turn allowed the calculation of the uncertainty on the effective noise levels. Results: This new estimate of uncertainty (6 to 7 dB) is significantly larger than most previous estimates, which range between 4 and 5 dB when using objective data but with an improper uncertainty propagation, and around 3 dB when using REAT subjective data. We show that the revised new estimate of uncertainty is much more realistic as it includes contributions that are missed by the other methods. Conclusions: By plugging this revised estimate of uncertainty into the criterion for checking the acceptability of the HPD, a better assessment of the actual protection provided by the HPD itself is possible.

Keywords: Distribution function, ear plug, insertion loss, uncertainty

INTRODUCTION

The attenuation to noise that ear plugs are able to provide is known to show a very large variability from subject to subject,[1] which dwarfs all other contributions to the uncertainty on attenuation.[2] A significant fraction of such variability is due to the training that the subject has received and his/her motivation to use the ear plug at or near its ideal performance. While some progress towards a lower variability can be achieved by adequately training and motivating employees,[3,4] inevitable differences in individual approaches to self-protection will keep the distribution fairly wide no matter what.

An additional contribution to the observed variability can be attributed to biological (anthropometric) diversity. Custom-shaped ear plugs perform much better from this point of view, as they are built to fit the shape of the individual’s ear canal. However, very few companies provide customized ear plugs to their employees, whereas the vast majority of them rely on generic low-cost single-use ear plugs.

Not much is known on the shape of the distribution function of the insertion loss (IL) provided by an ear plug to a population of exposed workers. Common practice is based on the assumption that this distribution is approximately normal.

A widely used statistic that quantifies the insertion loss provided to a majority of subjects is the Assumed Protection Value (APV),[5] where

\[ \text{APV} = \text{Mean} - 1 \sigma. \]

Because in a normal distribution this corresponds to the 16th address for correspondence: Paolo Lenzuni, INAIL – Tuscany Regional Research Center, Via delle Porte Nuove 61, 50144 Firenze, Italy. E-mail: p.lenzuni@inail.it

Received: 12 January 2020 Revised: 27 May 2020 Accepted: 7 August 2020 Published: 24 December 2020

How to cite this article: Lenzuni P, Annesi D, Nataletti P. The Insertion Loss Distribution Function of An Ear Plug, and Its Implications for the Ear Plug Acceptability. Noise Health 2020;22:35-45.
performance to be carried out. This allows a more reliable and more realistic test of the acceptability of the HPD in a given acoustical context. Determined and a statistical test is performed to determine HPD. Finally, the uncertainty on this effective level is sound pressure levels that take into account the presence of the shape and the variance of the distribution of actual (effective) band frequencies are then used to derive information of the plug. The distribution functions of attenuation values at octave bands are used to quantify the minimum insertion losses of a specific model of ear plug. The E-A-Rfit method. A final compensation factor is introduced eardrum; 2) bone-conduction pathways that are missed by the eardrum; 3) acoustical coupling between the sound pressure levels that would be measured at the eardrum with and without the HPD as fitted, called Minimum Insertion Loss (IL). This is achieved by introducing two correction factors that adequately take into account: 1) the length of the probe tube between the microphone and the eardrum; 2) bone-conduction pathways that are missed by the E-A-RFit method. A final compensation factor is introduced to calculate the actual sound pressure at the eardrum starting from the value measured by the “internal” microphone.

Participants

Tests were carried out on 64 male and 36 female university students and staff. Their age range was 20 to 30 years, with mean 25.3 years and standard deviation 2.7 years. None of them reported any previous occupational exposure to noise as well as any previous experience in the use of ear plugs. They were all in good health and no ear-related pathologies, either previous or current, were reported. Given the extremely short signal duration (see the section on Experimental Design), exposure to noise in this work is well below any possible threshold for TTS. All tested subjects received adequate information about the exposure to noise implied by the test, and they all expressed a verbal informed consent.

The E-A-RFit method

The principles of the E-A-Rfit method are extensively described in the literature. In synthesis, the E-A-RFit system hardware consists of two microphones: an “external” microphone which measures sound pressure immediately outside the ear canal, and an “internal” microphone. This latter microphone is physically also located outside the ear canal, in order to minimize the invasiveness of the device. However, it is acoustically coupled to the region near the eardrum by means of a miniature probe which is inserted through the Hearing Protector Device (HPD) to be tested. The straightforward difference between the two sound pressure levels measured by the external and the internal microphone corresponds to the transmission loss (TR) of the HPD as fitted. This is later converted into the difference between the sound pressure levels that would be measured at the eardrum with and without the HPD as fitted, called Insertion Loss (IL). This is achieved by introducing two correction factors that adequately take into account: 1) the length of the probe tube between the microphone and the eardrum; 2) bone-conduction pathways that are missed by the E-A-RFit method. A final compensation factor is introduced to calculate the actual sound pressure at the eardrum starting from the value measured by the “internal” microphone.

Experimental design

All subjects have initially been trained to the use of the ear plug just before being tested, by means of a 5-minute video clip showing the correct insertion procedure. Each subject has been invited to seat at a distance of 0.5 m from a loudspeaker, in such a way that the loudspeaker-to-subject vector was aligned with the subject’s line of sight [Figure 1]. Each test has been carried out using a 15-second pink noise signal appropriate for measuring attenuations at octave bands between 125 to 8000 Hz.

For each tested subject, the sound pressure levels of the external and internal microphones have been recorded for each of the two ears. Two independent estimates of the insertion loss (IL) have accordingly been performed, one

| Frequency (Hz) | 125 | 250 | 500 | 1000 | 2000 | 4000 | 8000 |
|---------------|-----|-----|-----|------|------|------|------|
| **Insertion loss** | | | | | | | |
| Mean | 33.1 | 36.3 | 38.4 | 38.7 | 39.7 | 48.3 | 44.4 |
| St. Dev. | 5.0 | 7.4 | 6.2 | 5.6 | 4.3 | 4.5 | 4.4 |
| **SNR** | | | | | | | 37 |

Table 1: Nominal octave band insertion loss and SNR for the investigated ear plug. All values in dB.

Object of tests

The investigated ear plug is model 1100 of 3M. This is a typical general purpose ear plug with a conic shape near the bottom and a rounded shape near the head for better insertion.

Its low cost and good nominal performance [see Table 1] have made it a very popular choice by employers.

Individual and objective assessment of insertion loss provided by an ear plug has now been possible for about a decade using different approaches. The use of such methods in actual workplaces is however still limited and will hardly become widespread in the next years. Statistical methods are therefore still needed to derive a reliable estimate of the attenuation provided by a HPD to a worker.

In this work we adopt one objective method (E-A-Rfit) to measure individual insertion losses of a specific model of ear plug. The distribution functions of attenuation values at octave band frequencies are then used to derive information of the shape and the variance of the distribution of actual (effective) sound pressure levels that take into account the presence of the HPD. Finally, the uncertainty on this effective level is determined and a statistical test is performed to determine the acceptability of the HPD in a given acoustical context. This allows a more reliable and more realistic test of performance to be carried out.

**MATERIALS AND METHOD**

Object of tests

The investigated ear plug is model 1100 of 3M. This is a typical general purpose ear plug with a conic shape near the bottom and a rounded shape near the head for better insertion.

Its low cost and good nominal performance [see Table 1] have made it a very popular choice by employers.

Participants

Tests were carried out on 64 male and 36 female university students and staff. Their age range was 20 to 30 years, with mean 25.3 years and standard deviation 2.7 years. None of them reported any previous occupational exposure to noise as well as any previous experience in the use of ear plugs. They were all in good health and no ear-related pathologies, either previous or current, were reported. Given the extremely short signal duration (see the section on Experimental Design), exposure to noise in this work is well below any possible threshold for TTS. All tested subjects received adequate information about the exposure to noise implied by the test, and they all expressed a verbal informed consent.

The E-A-RFit method

The principles of the E-A-Rfit method are extensively described in the literature. In synthesis, the E-A-RFit system hardware consists of two microphones: an “external” microphone which measures sound pressure immediately outside the ear canal, and an “internal” microphone. This latter microphone is physically also located outside the ear canal, in order to minimize the invasiveness of the device. However, it is acoustically coupled to the region near the eardrum by means of a miniature probe which is inserted through the Hearing Protector Device (HPD) to be tested. The straightforward difference between the two sound pressure levels measured by the external and the internal microphone corresponds to the transmission loss (TR) of the HPD as fitted. This is later converted into the difference between the sound pressure levels that would be measured at the eardrum with and without the HPD as fitted, called Insertion Loss (IL). This is achieved by introducing two correction factors that adequately take into account: 1) the length of the probe tube between the microphone and the eardrum; 2) bone-conduction pathways that are missed by the E-A-RFit method. A final compensation factor is introduced to calculate the actual sound pressure at the eardrum starting from the value measured by the “internal” microphone.

Experimental design

All subjects have initially been trained to the use of the ear plug just before being tested, by means of a 5-minute video clip showing the correct insertion procedure. Each subject has been invited to seat at a distance of 0.5 m from a loudspeaker, in such a way that the loudspeaker-to-subject vector was aligned with the subject’s line of sight [Figure 1]. Each test has been carried out using a 15-second pink noise signal appropriate for measuring attenuations at octave bands between 125 to 8000 Hz.

For each tested subject, the sound pressure levels of the external and internal microphones have been recorded for each of the two ears. Two independent estimates of the insertion loss (IL) have accordingly been performed, one
for each ear. All measurements have been carried out in May 2019.

Statistical analysis
Insertion loss data for the left and the right ear have been mutually compared using a t-test in order to detect any hypothetical statistically significant differences. As no difference emerged at the \( P=0.05 \) level for any tested frequency, the value used in subsequent analysis has been taken as the average of the left and right IL.

Statistical calculations have mostly been carried out using Excel® spreadsheets with custom-built macros. A minor part has been performed using the data analysis software Kyplot.

RESULTS
Statistical distributions of insertion losses
Figure 2 shows the distribution functions of the measured insertion losses at all octave bands between 125 and 8000 Hz. All distributions are very wide, with 5th and 95th quantiles often separated by more than 20 dB.

As a general trend, the mode of the distribution increases as frequency increases. Distributions tend to be roughly symmetric at low frequency, and become more and more asymmetric as frequency increases. At 2000 Hz and above, all distributions show a very steep shoulder on the high side and a very pronounced tail on the low side.

Gender difference
No separate analysis of the distribution functions of insertion losses in the male-only (M) and female-only (F) sub-samples has been carried out, due to the limited size of both sub-

samples. The mean values of the insertion losses in the M and F sub-samples\textsuperscript{[15]} show that:
(1) the insertion loss in both sub-samples is almost identical (± 2 dB) at all frequencies \( f \geq 500 \) Hz;
(2) there is some evidence that the insertion loss might be higher in the F sub-sample at 125 Hz and 250 Hz. However the difference of the two means found in our study (3–3.5 dB) is not statistically significant at the 95% level, due to the limited size of the two sub-samples.

Additional research focused in particular on female subjects has been scheduled, which could lead to more robust conclusions on this topic.

Compliance with normative limits
EC Directive 2003/10/CE\textsuperscript{[16]} states in its article 6.1.c that “individual hearing protectors shall be so selected as to eliminate the risk to hearing or to reduce the risk to a minimum”.

The qualitative concept of reducing the risk to a minimum has later been quantified by EN 458\textsuperscript{[17]} that shows in its Table A.4

Table 2: Range of acceptability for \( L'_{p,A,eq} \) as specified in EN 458:2016\textsuperscript{[17]}

| Level effective to the ear (\( L'_{p,A,eq} \) in dB) | Protecting rating |
|-----------------------------------------------|-------------------|
| Greater than \( L'_{NR} \)                    | Insufficient      |
| Between \( L'_{NR} \) and \( L'_{NR} - 5 \)  | Acceptable        |
| Between \( L'_{NR} - 5 \) and \( L'_{NR} - 10\) | Good              |
| Between \( L'_{NR} - 10 \) and \( L'_{NR} - 15\) | Acceptable        |
| Less than \( L'_{NR} - 15 \)                 | Risk of over-protection |

Figure 1: Experimental set-up.
(here replicated as Table 2) the range of acceptable noise equivalent levels.

In synthesis, the quantity $L'_{p,A,eq}$ must lie between the national reference ($L'_{NR}$) and ($L'_{NR} - 15$ dB). The lower limit is aimed at preventing overprotection and is of no relevance in this context. So the only significant compliance test is that $L'_{p,A,eq}$ is no larger than $L'_{NR}$. The quantity

$$L'_{p,A,eq} = 10 \log \left[ \sum_{n=1}^{N} 10^{0.1 \left( L_{p,A,n} + A_n - H_n \right)} \right] (1)$$

is improperly defined\cite{17} as “the level effective to the ear”. Indeed, as shown by equation (1), it corresponds to the

---

**Figure 2:** Experimental distributions of insertion losses at individual octave bands between 125 Hz and 8000 Hz.
environmental sound pressure A-weighted level which would give the same tympanic pressure as the one that exists when the HPD is worn. In this paper the quantity \( L'_{p,A,eq} \) shall be indicated as “effective equivalent A-weighted sound pressure level” or just “effective equivalent sound pressure level”. In equation (1) the sum is carried out over the \( N = 7 \) octave bands from 125 to 8000 Hz. Simple statistical methods\(^{[18]}\) indicate that the compliance test has the form:

\[
L'_{p,A,eq} + U(L'_{p,A,eq}) < L'_{NR} \tag{2}
\]

Here \( U(L'_{p,A,eq}) \) is the extended uncertainty associated to \( L'_{p,A,eq} \). So that the quantity \( L'_{p,A,eq} + U(L'_{p,A,eq}) \) on the left hand side of equation (2) is the upper extreme of the one-sided confidence interval on \( L'_{p,A,eq} \). If the inequality (2) is fulfilled, there is a known probability (usually set at 95%) that \( L'_{p,A,eq} \) is indeed lower than \( L'_{NR} \).

There are two methods to calculate \( U(L'_{p,A,eq}) \): an analytical method (to be discussed in the next section Uncertainty - analytical method), and an empirical method (to be discussed in the ensuing section Uncertainty - empirical method).

### Uncertainty-analytical method

#### Full method and simplified method

In the analytical method, the extended uncertainty \( U(L'_{p,A,eq}) \) is calculated as a multiple of the uncertainty \( u(L'_{p,A,eq}) \). The latter is in its turn calculated by appropriately combining all the uncertainties on the variables requested for the calculation of \( L'_{p,A,eq} \) that is the individual A-weighted octave band levels \( (L_{p,A,eq,n}) \), and the octave band insertion losses \( (IL_n) \). Equation (16) of ISO/IEC Guide 98-3\(^{[19]}\):

\[
\sigma^2(y) = \sum_{j=1}^{m} c_j^2 \sigma^2(x_j) + 2 \sum_{j=1}^{m-1} s_{kj} c_j c_k u(x_j)u(x_k) r(x_j,x_k) \tag{3}
\]

provides the formal template for the calculation of the uncertainty on a dependent variable \( y \).

In equation (3):
- \( c_j \) are the sensitivity coefficients;
- \( x_j \) are the variables;
- \( u(x_j) \) are the uncertainties on \( x_j \);
- \( r(x_j,x_k) \) are the correlation coefficients between variables.

As shown in equation (1), \( L'_{p,A,eq} \) depends on \( N \) environmental octave band levels \( L_{p,A,eq,n} \) and \( N \) octave band insertion losses \( IL_n \). Environmental levels and insertion losses can be assumed to be mutually independent. For the specific case under investigation, equation (3) can then be written as the sum of two contributions: the first one includes the variances of \( L_{p,A,eq,n} \) and the variances of \( IL_n \):

\[
\sigma^2(L'_{p,A,eq}) = \sum_{n=1}^{N} \left( \frac{\partial L'_{p,A,eq}}{\partial L_{p,A,eq,n}} \right)^2 \sigma^2(L_{p,A,eq,n}) + \left( \frac{\partial L'_{p,A,eq}}{\partial IL_n} \right)^2 \sigma^2(IL_n) \tag{4a}
\]

while the second one takes into account the mutual correlation among \( L_{p,A,eq,n} \) at different octave bands as well as the mutual correlation among \( IL_n \) at different octave bands:

\[
\sigma^2(L'_{p,A,eq}) = 2 \sum_{n=1}^{N} \sum_{m=n+1}^{N} \left( \frac{\partial L'_{p,A,eq}}{\partial L_{p,A,eq,n}} \right) \left( \frac{\partial L'_{p,A,eq}}{\partial L_{p,A,eq,m}} \right) u(L_{p,A,eq,n})u(L_{p,A,eq,m}) r(L_{p,A,eq,n},L_{p,A,eq,m}) \]

+ \sum_{n=1}^{N} \sum_{m=n+1}^{N} \left( \frac{\partial L'_{p,A,eq}}{\partial IL_n} \right) \left( \frac{\partial L'_{p,A,eq}}{\partial IL_m} \right) u(IL_n)u(IL_m) r(IL_n,IL_m)
\]

Correlation terms, whose calculation is somewhat cumbersome, are usually ignored in current practice, which is equivalent to assume that both individual A-weighted octave band levels \( (L_{p,A,eq,n}) \) and individual insertion losses \( (IL_n) \) are independent of one another. In this paper, two values of \( u(L'_{p,A,eq}) \) have been computed: one using only equation (4a), which will be referred to as “analytical simplified”; another one using both equations (4a) and (4b), which will be referred to as “analytical full”.

Finally, the extended uncertainty \( U(L'_{p,A,eq}) \) has been calculated as a multiple of \( U(L'_{p,A,eq}) \):

\[
U(L'_{p,A,eq}) = 1.645 u(L'_{p,A,eq}) \tag{5}
\]

where the factor 1.645 assumes a mono-lateral interval with 95% confidence level.

#### Uncertainty on octave band levels of the environmental noise

As extensively discussed in the previous section, the calculation of \( U(L'_{p,A,eq}) \) requires the knowledge of the uncertainties on octave band levels in the work environment \( u(L_{p,A,eq,n}) \) and of octave band insertion losses \( u(IL_n) \). Values of \( u(L_{p,A,eq,n}) \) result from three contributions: random fluctuations of the noise itself; uncertainty due to instrumentation; uncertainty due to the microphone position.

(a) Random fluctuations: When measurements are taken in compliance with the task-based strategy of ISO 9612,\(^{[20]}\) differences among A-weighted values due to random fluctuations of noise, must not exceed 3 dB. In principle, uncertainties in individual octave band levels could be substantially larger, if significant anti-correlation exists between values in different bands. However tests carried out in the Acoustic Laboratory of the INAIL Research center (Monteporzio Catone, Rome, Italy) show that for a variety of industrial sources, uncertainties in the most relevant octave bands (those with a significant fraction of the total energy) do not exceed 2 dB. Slightly larger than average values can occur in low-frequency noise, because A-weighting gives lower weight to low frequencies. As a general rule, larger than average values occur in broadband noise, that is when significant energy appears over many octave bands.

(b) Instrumentation: The uncertainty in individual octave bands due to instrumentation has been found to be below 0.5 dB in all octave bands of interest in this study.\(^{[21]}\)

(c) Microphone position: A rough estimate of this contribution has been set at 1 dB for A-weighted values regardless of the acoustic field.\(^{[20]}\) Uncertainties in individual octave bands due to measurement position have been quantified by carrying out tests with different microphone positions in different acoustic fields. Such tests indicate that uncertainties in
the most relevant octave bands do not exceed 1.5 dB. As indicated above for random fluctuations, larger than average values occur in broadband noise.

The overall uncertainties on individual octave band levels of workplace environmental noises are of order 2.5 dB or less, with significant contributions from both random noise fluctuations and microphone position.

**Uncertainty on octave band insertion losses**

Uncertainties on octave band insertion losses u(ILn) have been quantified using the standard deviations of the distributions found in this work.

**Uncertainty on the effective equivalent sound pressure level**

Because the two sensitivity coefficients \( \frac{\partial L_{\text{p,Aeq,n}}}{\partial L_{\text{p,n}}} \) and \( \frac{\partial L_{\text{p,Aeq,n}}}{\partial u(L_{\text{p,n}})} \) are identical, equation (4a) shows that contributions to u(L′p,Aeq,n,eq) are proportional to the two uncertainties, on octave band insertion losses u(ILn), and on octave band environmental noise. Given the numerical values presented in Figure 2 and the estimates provided in 3.4.3, the uncertainty on the effective noise equivalent level is dominated by uncertainties on octave band insertion losses u(ILn).

**Simplified method using “trained subject-fit” data**

An additional estimate of both L′p,Aeq,n and U(L′p,Aeq,n) has been found using again the simplified analytical method, this time setting ILn and u(ILn) equal to the mean values and standard deviations provided by the ear plug manufacturer. These values result from a procedure known as “trained subject-fit”. It is well known that both mean values and standard deviations determined with this procedure are unrealistic. Mean values are gross overestimates, and probably trace the ideal performance much more than the average workplace performance. On the opposite, standard deviations are clear underestimates, since the extremely rigid experimental procedure removes much of the variability expected in the sample.

**Uncertainty-empirical method**

In the empirical method, no assumption is made about the mutual dependency of individual octave band levels and insertion losses. An input environmental noise Lp,eq with a given octave band spectrum is assumed. By combining Lp,eq with each of the 100 experimentally determined insertion loss octave band spectra, and applying A-weighting, 100 octave band spectra of L′p,Aeq,n are calculated, with \( n = 1 \) to \( n = 7 \) corresponding to octave band center frequencies from 125 to 8000 Hz. Figure 3 shows the probability distributions of the effective equivalent sound pressure level L′p,Aeq,n at one representative low (250 Hz, \( n = 2 \)) and high (2000 Hz, \( n = 5 \)) frequency, assuming a triangle-shaped environmental noise spectrum Lp,eq.

In the empirical method, U(L′p,Aeq,n) has not been calculated as a multiple of u(L′p,Aeq,n), but directly as the difference between the mean and the upper 95th quantile of the distribution of L′p,Aeq,n, as shown in Figure 4.

**DISCUSSION**

Table 3 compares the mean values of the effective equivalent sound pressure level L′p,Aeq and the associated extended uncertainties U(L′p,Aeq) calculated using the four different procedures previously outlined: the empirical (E) method, columns 2 and 3; the analytical full (AF) method applied to the experimental values found in this work, columns 4 and 5; the analytical simplified (AS) method applied to the experimental values found in this work, columns 6 and 7; the analytical simplified method applied to the manufacturer-declared values (ASI) found according to the “trained subject-fit” procedure, columns 8 and 9.
This comparison is carried out for four different input environmental noises, characterized by different frequency spectra shown in Figure 5. Such spectra have been selected to represent extreme cases, so that any workplace noise would give results within the range explored in this work. All workplace noises have the same A-weighted global level $L_{p,A,eq} = 105$ dB(A). The information shown in Table 3 on the extended uncertainty has also been displayed in Figure 6 for improved clarity of presentation.

The following are the most remarkable points:

1. The mean values are highest in the empirical method than in the analytical method. This is due to the non-linearity of the algorithm that calculates $L'_{p,A,eq}$. In the analytical method, $L'_{p,A,eq}$ is found as the energetic sum over the seven relevant octave bands of the mean sound levels calculated by subtracting the MEAN insertion loss. In the empirical method, the sum over octave bands is carried out for each tested subject, and the mean over the 100 tested subjects is performed in the last stage of the calculation. Because some of the subjects display a very small attenuation, some of the effective levels $L'_{p,A,eq}$ are particularly high, which forces a higher final value of the mean $L'_{p,A,eq}$.

2. The mean values are lowest in the analytical simplified method using “trained subject-fit” data. This is simply due to the grossly overestimated values of insertion losses produced following the “trained subject-fit” procedure.

Table 3: Values of $L'_{p,A,eq}$ and $U(L'_{p,A,eq})$ resulting from: the empirical method (columns 2 and 3), the analytical full method applied to experimental values found in this work (columns 4 and 5), the analytical simplified method applied to experimental values found in this work (columns 6 and 7), the analytical simplified method applied to manufactured-declared values (columns 8 and 9).

| Shape | Empiric This work | Analytic full This work | Analytic simplified This work | Analytic simplified ISO 4869-1 |
|-------|------------------|------------------------|-------------------------------|-------------------------------|
|       | $L'_{p,A,eq}$    | $U(L'_{p,A,eq})$        | $L'_{p,A,eq}$                | $U(L'_{p,A,eq})$              | $L'_{p,A,eq}$                | $U(L'_{p,A,eq})$              |
| a     | Flat             | 72.5                   | 11.1                          | 70.7                          | 12.3                          | 70.7                          | 7.3                          |
| b     | Triangle         | 72.7                   | 11.0                          | 71.1                          | 12.4                          | 71.1                          | 7.7                          | 65.4                          | 4.3                          |
| c     | Rising           | 70.8                   | 12.7                          | 69.2                          | 10.7                          | 69.2                          | 7.6                          | 62.7                          | 4.0                          |
| d     | Falling          | 74.3                   | 14.4                          | 72.2                          | 14.9                          | 72.2                          | 7.4                          | 66.8                          | 4.6                          |

Figure 4: Estimation of the extended uncertainty $U(L'_{p,A,eq})$ in the empirical method.
(3) Extended uncertainties $U(L'_{p,A,eq})$ calculated using the analytical simplified method based on “trained subject-fit” data are much smaller than those based on this work’s data, because uncertainties on individual octave band insertion losses are much smaller themselves.

(4) Extended uncertainties are much smaller in the analytical simplified method than in the empirical method, when applied to the same dataset. This reflects, as previously noticed, the missing terms of covariance in the simplified analytical approach, which cannot be ignored given the substantial mutual correlation of individual insertion losses in different octave bands. This conclusion might have been anticipated from the shapes of the distributions shown in Figure 3. In the case of uncorrelated variables, the combination of many independent distributions would result in a normal (hence symmetrical) distribution, as dictated by the central limit theorem. On the opposite, the asymmetric shapes of the distributions shown in Figure 3 point to significant correlation between the variables.

(5) Extended uncertainties calculated using the analytical full method are roughly comparable to those calculated using the empirical method. This was of course expected given that both methods take into account the actual mutual correlations between octave band insertion losses. The small differences are mostly attributable to the approximate empirical determination of the 95th quantile in a sample of 100 and the deviation of the distribution from a true normal distribution which is implicitly assumed by the use of the coverage factor 1.645 in equation (5).

Assuming a national reference level $L'_{NR} = 80\,\text{dB}(A)$ (as indicated by the Italian national technical standard on occupational exposure to noise\textsuperscript{[22]}), the compliance test for acceptability (equation 2) is passed if the methods “analytic simplified” and “analytic simplified ISO” are used. The test is failed if the methods “analytic full” and “empirc” are used [Figure 7].

A calculation of the uncertainty using the analytical full method that includes correlation terms is probably too

---

**Figure 5:** Spectral shapes of environmental noises used to calculate the values of Table 3: Flat (a), Triangle (b), Rising (c), Falling (d).
complex for the average user. A possible shortcut is to use the “Approximate Full” (AppF) value

\[ u_{\text{AppF}}(L_{\text{p,A,eq}}) = K_M \times u_M(L_{\text{p,A,eq}}) \]  

found by multiplying the estimate \( u_M(L_{\text{p,A,eq}}) \) obtained using a generic (simplified) method \( M \), by a method-dependent correction factor \( K_M \). Based on values displayed in Table 3, we estimate that actual uncertainties are 1.5 to 2 times larger than zero-correlation uncertainties (method AS), and 2 to 3 times larger than trained subject-fit uncertainties (method ASI). Recommended correction factors are:

1. \( K_{\text{AS,Method B}} = 1.75 \), to be adopted when “inexperienced subject-fit” data (ANSI/ASA S12-6[8] Method B) are used;
2. \( K_{\text{AS,Method A}} = 2.5 \), to be adopted when “trained subject-fit” data (ISO 4869-1[7] or ANSI/ASA S12-6[8] Method A) are used.

**CONCLUSIONS**

The traditional statistical method that quantifies the insertion loss of an ear plug using the laboratory “trained subject-fit” procedure[8] (Method A), has long been known to result in strong overestimates of the mean octave band values, as well as strong underestimates of the associated standard deviations. Individual methods are clearly much more reliable, but their popularity is still limited, so statistical approach will remain in use for quite some time.

Estimates based on objective estimates as well as on the laboratory “inexperienced subject-fit” procedure[8] (Method B) mark a significant improvement in both respects. However, predictions of the effective equivalent A-weighted sound pressure levels, often used to verify that the vast majority of workers are adequately protected, still fail to approach real workplace values unless the existing correlation between octave band insertion losses are taken into account. This study shows in fact that estimates of the effective sound pressure values derived from actual empirical distributions of insertion losses closely trace values calculated including correlation terms.

Because the full calculation is somewhat complex, we recommend that an approximate estimate of the uncertainty/expanded uncertainty is derived by multiplying uncertainties found using simplified methods by a factor \( K_M \) that ranges between 1.75 and 2.5. By plugging this new estimate of uncertainty into the criterion for checking the acceptability of the hearing protector, a better assessment of the actual protection provided by the HPD is possible.

**Acknowledgements**

The authors gratefully acknowledge 3M Italia for providing the experimental equipment used in this project.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.
REFERENCES

1. Neitzel R, Somers S, Seixas N. Variability of real-world hearing protector attenuation measurements. Ann Occup Hyg 2006;50:679-91

2. Lima FR, Gerges SNY, Rodrigo T, Zmijevski L, Bender DF, Gerges RNC. Uncertainty calculation for hearing protector noise attenuation measurements by REAT method. J Braz Soc Mech Sci & Eng 2010;32

3. Joseph A, Punch J, Stephenson MR, Paneth N, Wolfe EW, Murphy WJ. The effects of training format on earplug performance. Int J Audiol 2007;46:609-18

4. Murphy WJ, Stephenson MR, Byrne DC, Witt B, Duran J. Effects of training on hearing protector attenuation. Noise Health 2011;13:132-41

5. ISO 4869-2:2018, Acoustics – Hearing protectors – Part 1: estimation of effective A-weighted sound pressure levels when hearing protectors are worn, International Organization for Standardization, Geneve, Switzerland

6. Murphy WJ, Franks JR, Berger EH, Behar A, Casali JG, Dixon-Ernst C, Krieg EF, Mozo BT, Ohlin D, Royster LH. Development of a new standard laboratory protocol for estimating the field attenuation of hearing protection devices. Part I – research of working group 11, accredited standards committee S12, noise. J Acoust Soc Am 1996;99:1506-26

7. ISO 4869-1:2018, Acoustics – Hearing protectors – Part 1: subjective method for the measurement of sound attenuation, International Organization for Standardization, Geneve, Switzerland

8. ANSI/ASA S12.6-2016, Methods For Measuring The Real-Ear Attenuation Of Hearing Protectors, American National Standards Institute, Washington DC, United States of America

9. Berger EH, Franks J, Lindgren F. International Review of Field Studies of Hearing Protector Attenuation, in Scientific Basis of Noise-Induced Hearing Loss, edited by Axlesson A., Borchgrevink H., Hamernik R.P., Hellstrom P., Henderson D., Salvi R.J., Thieme Medical Pub. Inc., New York, NY, 361-377 (1996)

10. Royster JD, Berger EH, Merry CJ, Nixon CW, Franks JR, Behar A, Casali JG, Dixon-Ernst C, Kieper RW, Mozo BT, Ohlin D, Royster LH. Development of a new standard laboratory protocol for estimating the field attenuation of hearing protection devices. Part I – research of working group 11, accredited standards committee S12, noise. J Acoust Soc Am 1996;99:1506-26

11. Berger EH. What is a Personal Attenuation Rating (PAR)?. 3M Occupational Health & Environmental Safety Division, E-A-R 07-21/HP (2010)

12. Berger EH, Voix J, Kieper RW, Le Coq C. Development and validation of a field microphone-in-real-ear approach for measuring hearing protector attenuation. Noise Health 2011;13:163-75

13. Hager LD. Fit-testing hearing protectors: an idea whose time has come. Noise Health 2011;13:147-51

14. Schulz TY. Individual fit-testing of earplugs: a review of uses. Noise Health 2011;13:132-41

15. Annesi D, Nataletti P, Galbiati C, Peruch D, Alfaro Degano G, Coltrinari G, Lippiello D, Vestracci A, Lenzuni P. Misure di attenuazione di un inserto auricolare mediante metodica E-A-Rfit, Proceedings of the Conference dBA 2019, Modena, Italy, October 16-17, 2019 (in italian)

16. Council and Parliament Directive 2003/10/EC of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise). Official Journal of the European Union L42/38, 15.2.2003

17. EN 458:2015 Hearing protectors – recommendations for selection, use, care and maintenance. Guidance document, European Committee for standardization, Brussels, Belgium

18. ISO/IEC Guide 98-4:2012, Uncertainty of measurement – Part 4: Role of measurement uncertainty in conformity assessment, International Organization for Standardization, Geneve, Switzerland

19. ISO/IEC Guide 98-3:2008, Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995), International Organization for Standardization, Geneve, Switzerland

20. ISO 9612:2009, Acoustics – Determination of occupational noise exposure – Engineering method. International Organization for Standardization, Geneve, Switzerland
21. Payne R. Uncertainties in noise emission level measurements associated with the use of a sound level meter, ISO/TC 43/SC 1/WG 28 Discussion Paper (2003)

22. UNI 9432:2011, Acustica — Determinazione del livello di esposizione personale al rumore nell’ambiente di lavoro (in Italian)