Intra-Subject Fit Variability for Field Microphone-In-Real-Ear Attenuation Measurement for Custom Molded Earplugs

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Over the last few years, several field attenuation measurement systems (FAMS) have been introduced to the industrial marketplace to measure the individual end-user attenuation for some hearing protection devices (HPDs). Although individual measurement is necessary to determine whether a given user is properly protected in his or her real-life noise environment (assuming that the exposure level is known), one unknown remains with a FAMS measurement: how reliable are the predictions made from the instantaneous measurement (over a few minutes), for determining the attenuation that will be achieved later in the field (over months or years) by the end-user who may fit them slightly differently every time? This paper will address that question for one FAMS, the field microphone-in-real-ear (F-MIRE) measurement technique, and we will study, in the laboratory, how consistently subjects can fit and refit HPDs without assistance. A new metric, the intra-subject fit variability, will be introduced and will be quantified for custom-molded earplugs as fitted by inexperienced test subjects. This paper will present the experimental process used and statistical calculations performed to quantify the intra-subject fit variability. The number of successive refits required for a given prediction accuracy will also be presented, as well as the uncertainty component associated with the intra-subject fit variability when using an F-MIRE field attenuation measurement system.

1. INTRODUCTION

The goal of this study is to state how consistently a person can fit and refit a given HPD by himself or herself. Such a study is particularly important now that FAMS are commonly available to the hearing conservation community. Although FAMS may differ substantially in their methodology (a comprehensive list of FAMS available at the time of this writing exists[1]) they still have a common point: they only can take "snapshots" of the effective HPD attenuation. One could argue that the attenuation values reported by such FAMS are incomplete if no provision is made for how variable the fit of the HPD can be after the initial FAMS snapshot, hence the exact aim of the current study is to look at how consistently subjects can fit and refit HPDs without assistance. The FAMS that will be used in this study is the F-MIRE; it is currently only usable for insert HPDs (earplugs), but it was brought to the industry in 2001 and is one of the oldest and most documented objective FAMS.[2–7]

With the F-MIRE, the sound pressure levels in the ear canal (under the hearing protector) and those outside the HPD are simultaneously measured. Using suitable correction factors to account for known and quantifiable acoustic differences between the F-MIRE and REAT (real-ear attenuation at threshold),[3,5] the values can be used to accurately estimate the HPD's attenuation. The F-MIRE system incorporates a dual-element miniature microphone and associated proprietary technology. One section of the dual-element microphone couples through the earplug to pick up the sound pressure levels in the ear canal, and the other section measures the external sound field. Broadband pink noise is presented through a small loudspeaker in front of the subject with proper equalization for the speaker frequency response. The actual measurement takes about 10 seconds for one fit in one ear for the standard seven test frequencies from 125 Hz to 8 kHz, from which an overall noise reduction rating or personal attenuation rating (PAR) is calculated. Though the PAR appears to be an exact number, it also contains its own variability, albeit much less than in the classical approach of using mean laboratory data to make individual field predictions. The extent of variability in PAR is defined and explicitly provided with the measurement, as it will be presented in section 3.2. F-MIRE is currently commercially available under two brand names, SonoPass® from Sonomax and E-A-Rfit™ from 3M/Aearo. The latter system has the ability to test both custom and disposable earplugs designed with a probe tube to measure the occluded signal. The SonoPass® system version 3.2 was used in this study.

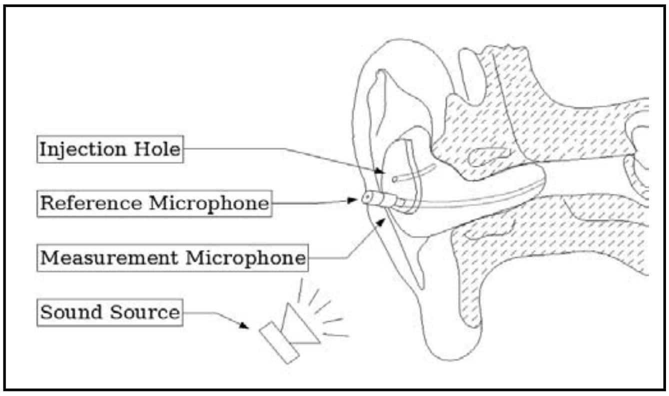

Figure 1. F-MIRE setup for an instrumented custom earplug with callouts for all important components.

2. EXPERIMENTAL PROTOCOL USED

Fifteen test subjects who had no experience with HPDs were recruited by the research team at Sonomax Hearing Healthcare. These inexperienced subjects met the requirements of "naive" subjects to be used in Method B of ANSI S12.6-2008.[8] An extra question about the test subjects' experience with custom earplugs was added ("Did you ever use a pair of custom-made earplugs?") and led to the rejection of four of the initial 15 test subjects. A total of seven female and eight male subjects were tested with an average age of 32 years old (SD = 8) ranging from 18 to 48 years old; two of 15 subjects were left-handed and the average number of times the subjects had worn HPDs was 44 (SD = 70), ranging from 0 to 208 times. The data used in this study were collected on 11 subjects tested with SonoCustom V3 S2/M2 earplug.

At the beginning of each subject's visit, a certified Sonomax technician molded a pair of SonoCustom V3 S2/M2 earplugs for the test subject, following the implementation process used in the industry. Each subject was then tested 10 times in a row on each ear for the F-MIRE attenuation provided by the custom earplug. The attenuation was first measured 10 times in a row on the right ear and then on the left ear.

3. EXPERIMENTAL RESULTS

For each of the N_s test subjects (index n_s), the attenuation ATT over the N_t trials (index n_t) for each of the 2 ears (index n_{rl}) was computed for the 7 octave bands (index n_f) for the custom earplug. The attenuation on the initial fitting ATT_{init} was also computed.

First the initial fitting attenuation and the trial fitting attenuations were analyzed. Then the distance to the mean attenuation was determined for each trial fitting attenuation. The variation per trial of the distribution of the distance to overall ear mean attenuation is then calculated. Finally, the number of refits required for proper estimation of the mean individual attenuation is presented.

3.1. Earplug attenuation results

The individual initial fitting attenuation $ATT_{init,ind}(n_s, n_f)$ is computed for each subject and each frequency as the average over the two ears of the initial fitting attenuation $ATT_{init}(n_s, n_{rl}, n_f)$:

$$ATT_{init,ind}(n_s, n_f) = \frac{1}{2} \sum_{n_{rl}=1}^{2} ATT_{init}(n_s, n_{rl}, n_f). \quad (1)$$

The average fitting attenuation $\overline{ATT}(n_s, n_{rl}, n_f)$ is computed for each subject, each ear, and each frequency as the average across all N_t trials of the fitting attenuations $ATT(n_s, n_t, n_{rl}, n_f)$:

$$\overline{ATT}(n_s, n_{rl}, n_f) = \frac{1}{N_t} \sum_{n_t=1}^{N_t} ATT(n_s, n_t, n_{rl}, n_f). \quad (2)$$

The individual fitting attenuation $ATT_{ind}(n_s, n_f)$ is computed for each subject and each frequency as the average over the two ears of the trial fitting attenuation $\overline{ATT}(n_s, n_{rl}, n_f)$:

$$ATT_{ind}(n_s, n_f) = \frac{1}{2} \sum_{n_{rl}=1}^{2} \overline{ATT}(n_s, n_{rl}, n_f). \quad (3)$$

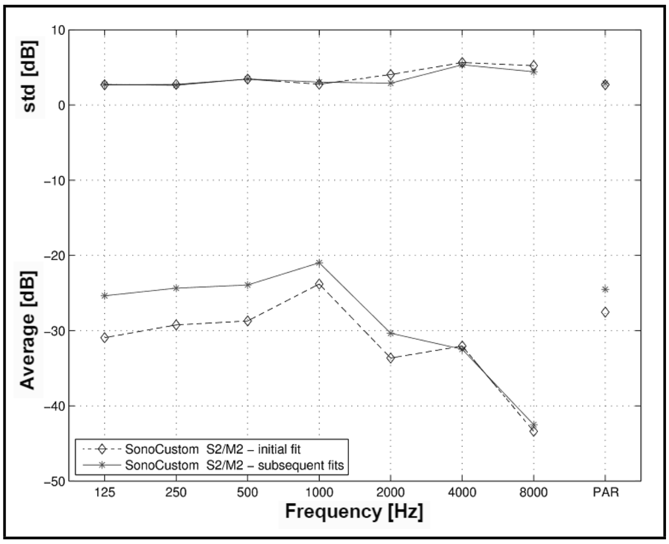

Figure 2. Average and standard deviation of the initial fit attenuation (in dotted line) and of the average of the 10 subsequent fits (in solid line).

The statistics of the individual trial fitting attenuation are analyzed by the average ($\overline{ATT_{ind}}(n_f)$) and the standard deviation ($\sigma_{ATT_{ind}}(n_f)$) according to the N_s subjects. The personal attenuation rating (PAR) is defined for each individual as:

$$PAR(n_s) = 10\log_{10}\left(\sum_{n_f=1}^{7} 10^{\frac{100+C(n_f)}{10}}\right) - 10\log_{10}\left(\sum_{n_f=1}^{7} 10^{\frac{100+A(n_f)-ATT_{ind}(n_s,n_f)}{10}}\right). \quad (4)$$

Figure 2 presents the average and standard deviation of the initial fit attenuation (dotted line), as well as the average and standard deviation of the fitting attenuation averaged across all 10 fits.

It can be seen in Fig. 2 that the average attenuation reported on the initial measurement (right after the earplug has been inflated to the subject's ear) is higher than the average attenuation measured on subsequent fits of the custom earplug. This behavior has been attributed to the use of a thick lubricant (composed of propylene glycol, glycerin, carboxymethylcellulose and sodium benzoate) during the molding of the custom earplug. This lubricant remains in place on the ear canal walls after the earplug has cured and is re-inserted for the measurement of the initial attenuation. This lubricant is more viscous than the water-based lubricant (water and glycerin) that is normally provided to the end-user and that will be used in this study for all subsequent fittings of the custom earplug. It hence provides a slightly increased average attenuation (by less than 3 dB), which will be further discussed in section 3.2.

3.2. Fit variability results: distance to ear mean attenuation

The distance to ear mean attenuation $\Delta FIT(n_s, n_t, n_{rl}, n_f)$ is defined as the difference between the fitting attenuation $ATT(n_s, n_t, n_{rl}, n_f)$ and the average fitting attenuation $\overline{ATT}(n_s, n_{rl}, n_f)$:

$$\Delta FIT(n_s, n_t, n_{rl}, n_f) = ATT(n_s, n_t, n_{rl}, n_f) - \overline{ATT}(n_s, n_{rl}, n_f). \quad (5)$$

The statistics of the distance to ear mean attenuation are analyzed by the average $\overline{\Delta FIT}(n_f)$ and the standard deviation $\sigma_{\Delta FIT}(n_f)$ according to the $N_{\Delta FIT} = N_s \times N_t \times 2$ ($220 = 11 \times 10 \times 2$) measurements of distance to ear mean attenuation.

Similarly, the distance to initial attenuation $\Delta FIT_{init}(n_s, n_t, n_{rl}, n_f)$ is defined as the difference between the fitting attenuation $ATT(n_s, n_t, n_{rl}, n_f)$ and the initial fitting attenuation $ATT_{init}(n_s, n_{rl}, n_f)$:

$$\Delta FIT_{init}(n_s, n_t, n_{rl}, n_f) = ATT(n_s, n_t, n_{rl}, n_f) - ATT_{init}(n_s, n_{rl}, n_f). \quad (6)$$

To assess the standard deviation of the values of ΔFIT, given that the 10 repeated measurements on the same subject cannot be treated as if they were independent, the pooled standard deviation defined below is used:

$$s_{\Delta FIT}(n_f) = \sqrt{\frac{1}{N_s 2} \sum_{n_s=1, n_{rl}=1}^{N_s, 2} \sum_{n_t=1}^{N_t} \frac{\Delta FIT(n_s, n_t, n_{rl}, n_f)^2}{N_t - 1}}. \quad (7)$$

Table 1 presents the standard deviation of the distance to ear mean attenuation (obtained from Eq. 7).

Table 1. Standard deviation of the distance to ear mean attenuation $\Delta FIT(n_f)$.

Frequency [Hz]	125	250	500	1000	2000	4000	8000	PAR
$s_{\Delta FIT}(n_f)$ [dB]	3.9	3.8	3.3	2.9	3.5	3.0	4.7	2.8

It can be seen in Table 1 that the standard deviation of the distance to ear mean attenuation allows us to quantify how consistently an individual can fit and refit an HPD. The distance to ear mean attenuation for the overall PAR value has been computed using Eq. 5 and Eq. 6, and substituting the attenuation variables by their corresponding PAR values determined with Eq. 4.

The distribution of the distance to ear mean attenuation for the overall PAR value has also been presented as histograms in Fig. 3, either as the distance to ear mean attenuation or as the distance to initial attenuation.

It can be seen in Fig. 3 (in black) that the distribution of the distance to mean overall PAR attenuation values looks like a normal distribution, but again, the 220 values of distance to mean have been obtained from repeated measurements and therefore cannot be treated as independent. It can also be clearly seen that when using the initial attenuation value (measured right after the first reinsertion of a freshly cured custom earplug), the histogram (in gray) is no longer centered on zero, but rather on –3 dB, confirming the bias introduced by the presence of a thick lubricant.

3.3. Variation per trial of the distribution of the distance to overall ear mean attenuation

The variation per trial of the distribution of the distance to overall ear mean attenuation has also been considered. Figure 4 (left chart) presents the average (solid gray line), standard deviation (gray vertical error bar) and histogram (gray bars) of the distance to overall ear mean attenuation for each of the ten trials. The distance to initial attenuation for each of the ten trials has been plotted in Fig. 4 (right chart).

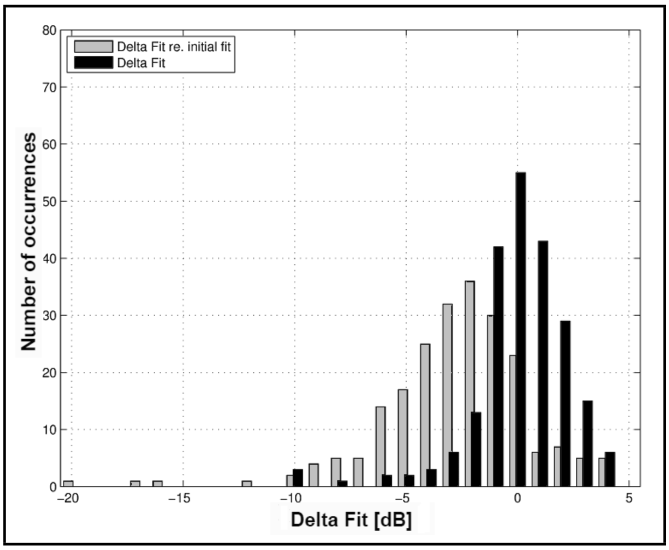

Figure 3. Histogram of the distance to ear mean attenuation ΔFIT (in black) and of the distance to initial overall PAR attenuation ΔFIT_{init} (in gray).

It can clearly been seen on Fig. 4 how consistent the subjects are in fitting their earplugs. What is striking is to see that some outliers (that are spread across several test subjects) can happen and, since they can reach up to –18 dB, the outliers are typically lowering the average trial attenuation.

One can easily see with Fig. 4 that the instant snapshot measurement of a user's HPD attenuation using a FAMS system can be dramatically affected by the consistency of how an HPD can be fitted and refitted over time. One way to improve the accuracy and precision of such instantaneous measurement would be to have more than one fitting of the same HPD. The next section will focus on calculating the minimal number of fits that should be conducted to reach a given level of confidence in the reported attenuation value.

3.4. Number of refits required for proper estimation of the mean individual attenuation

In the envisioned practical use of the developed field measurement system, the user is able to perform several measurements of the attenuation he/she is getting after each time he or she refits the earplugs. This allows a realistic assessment of the typical individual attenuation that he/she could get. Obviously, each refit of the product and measurement of the earplug attenuation has a cost: it takes approximately one minute to refit and re-measure the attenuation of a pair of earplugs. Whether there is an optimal number of refits that would both ensure a good estimation of the average attenuation while minimizing the number of refits to be done is something that remains to be determined. A "precision cost" analysis can be conducted by considering both the time spent and the gain on the size of confidence interval of the estimator of the mean attenuation.

The bilateral symmetrical confidence interval ϵ for the mean individual attenuation can be calculated from the following equation:[9]

$$\epsilon = t\left(\nu, 1 - \frac{\alpha}{2}\right) \frac{s_{\Delta FIT}}{\sqrt{n}}, \quad (8)$$

where n is the number of individual fit measurement (less than

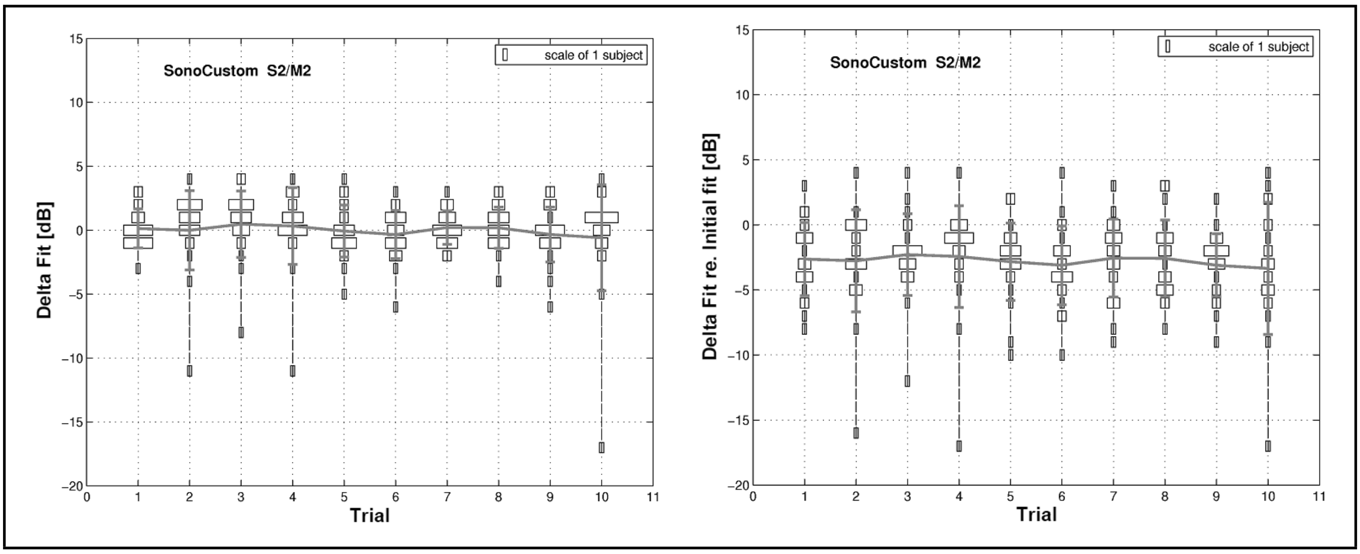

Figure 4. Average (solid gray line), standard deviation (gray vertical error bar) and histogram (gray bars) of the distance to overall ear mean attenuation for each of the ten trials (left chart) and of the distance to overall initial attenuation for the custom earplug (right chart).

30), s is the estimate of σ, which is the standard deviation of the sampling distribution (assumed to be the one measured from the current experiment per Eq. 7), and $t\left(\nu, 1-\frac{\alpha}{2}\right)$ is the Student-Fisher value for $\nu = n-1$ degree of freedom and leaving an area of $\frac{\alpha}{2}$ to the right.

The precision cost obtained as the product of the confidence interval and the extra test duration (assuming 1 minute per measurement) is presented in Table 2. It can be seen in Table 2 that the Student-Fischer value is decreasing much faster than the $\frac{1}{\sqrt{n}}$ term and the precision cost reaches minimal values very quickly.

Table 2. Detailed calculation of the precision cost.

n	$s_{\Delta FIT}$	ν	$\epsilon_{(95\%)}$	$\epsilon_{(99\%)}$	$\frac{1}{\sqrt{n}}$	$n \cdot \epsilon_{(95\%)}$	$n \cdot \epsilon_{(99\%)}$
2	2.8	1	25.16	126.03	0.71	50.31	252.06
3	2.8	2	6.96	16.04	0.58	20.87	48.13
4	2.8	3	4.46	8.18	0.5	17.82	32.71
5	2.8	4	3.48	5.77	0.45	17.38	28.83
6	2.8	5	2.94	4.61	0.41	17.63	27.65
7	2.8	6	2.59	3.92	0.38	18.13	27.46
8	2.8	7	2.34	3.46	0.35	18.73	27.71
9	2.8	8	2.15	3.13	0.33	19.37	28.19
10	2.8	9	2.00	2.88	0.32	20.03	28.77

Figure 5 shows the precision cost in dB minutes as a function of the number of measurements. It can be seen that measurements should be conducted at least four times and that the lowest precision cost is achieved at or about five measurements for reasonable risk (95% confidence interval) or around seven measurements for even lower risk (99% confidence).

4. RECOMMENDATION

Based on the previous observations, it appears to be clear that the initial fit variability represented by $s_{\Delta FIT}$ of the HPD must be accounted for inside any FAMS, since these systems are aiming to determine the level of attenuation users are getting in the field with their HPD in a fast and objective manner. The recommended implementation of the intra-subject fit variability for a FAMS system is illustrated in Fig. 6, which represents a screenshot of the SonoPass software V3.2.

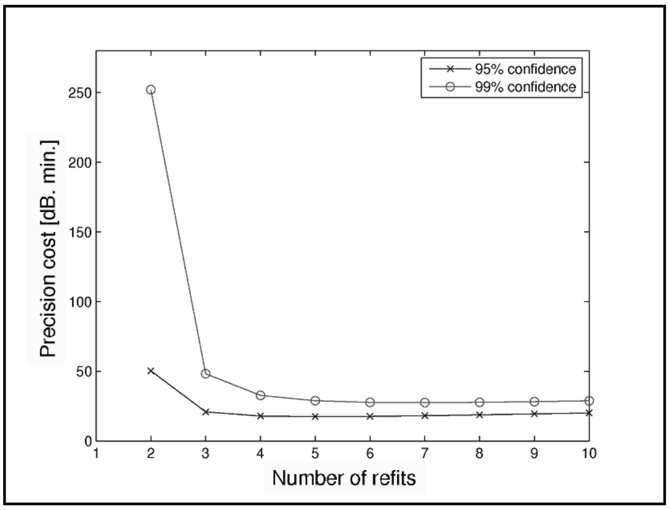

Figure 5. Precision cost according to the number of refits necessary for confidence intervals of 95% and 99%.

Figure 6 shows that the overall PAR value is presented on a normal distribution (which represents the typical attenuation that user can get with such HPD) with two horizontal error-bars. One error bar indicates the laboratory variability, which includes both the measurement uncertainty and the fit variability across laboratory test subjects, and spectral variability across noises. If sufficient repeated measurements are conducted on the employee in question, then a second uncertainty bar is shown, labeled individual variability. As the name implies, it is based on the variability in that individual's own data, while still including the measurement and spectral variability components. That value may be larger than the laboratory value if the individual cannot consistently fit the plug as well as the test subjects, or it can indeed be smaller, if the user is more consistent in fitting the plug than a typical laboratory subject. When sufficient repeated measures are accomplished (four measures in the current system) the variability of those individual data are used for the computation of individual fit variability using Eq. 7.

When there is only time to capture a single measurement on the individual, the uncertainty is estimated by applying the fit

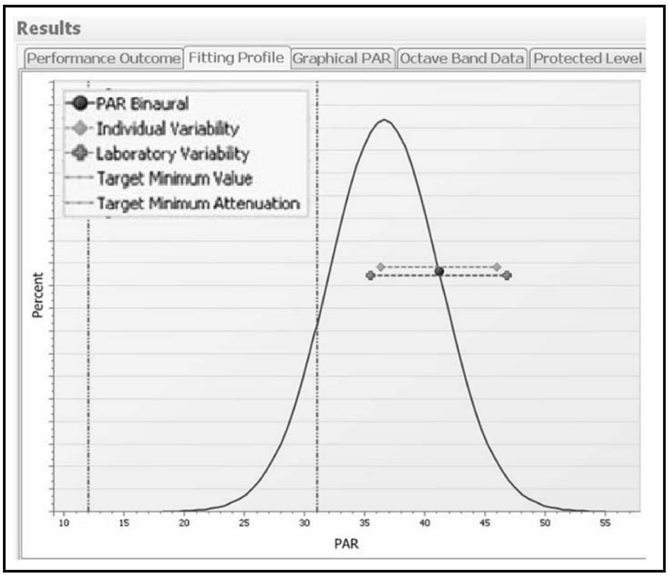

Figure 6. PAR value on the Results/Fitting Profile screen of SonoPass/EARfit software V3.2, clearly showing two error-bars accounting for both the F-MIRE measurement uncertainty and for the fit-variability: the fit-variability been assessed either on laboratory data (using the values presented in Fig. 5) or on individual data, if the subjects fits the earplug more than four times in a row.

variability values found in our prior laboratory experiments on 20 subjects. A better estimate can be gained if the employee fits the probed plug repeatedly so that the SonoPass system can measure his or her own variability.

5. CONCLUSIONS

FAMS are definitively powerful tools to measure the attenuation of HPDs. They can be used in many ways, and they are perfect to use in hearing conservation programs to select the most appropriate HPD for a user to wear, or to train and motivate that user to fit the HPD properly. Unfortunately, the personal attenuation rating value that such systems provide should be used with caution for two reasons. First, the PAR value, as any value provided by a physical instrument, should be provided along with an uncertainty statement that states the possible value of the measurement error if the same fit of that HPD was to be tested for the same subject using the REAT method (which is currently the standard in HPD attenuation measurement). Second, the uncertainty statement of the FAMS should also account for the individual or intra-subject fit variability of the HPD, as the current study clearly demonstrated that instantaneous snapshots of one's HPD may be far from the typical attenuation that this subject will get later in the field and that it is really dependent on the HPD type to be used. This study also revealed that the custom earplug used in this study may have a slight drawback in that the initial attenuation value might be overestimated by a few decibels because of the way these particular earplugs are delivered to the end-user (fitted on the spot with a thick lubricant). Further research should be conducted to remove that bias, such as the use of the water-based lubricant at the stage of making of these custom earplugs. Further experiments should also be conducted on other types of earplugs to estimate the typical individual fit variability that they provide.

Although this study made clear that the attenuation values reported by FAMS would be incomplete if no provision is made for the variability of the fit of the HPD after the initial FAMS snapshot, it should also be clear that such provision cannot take into account the abnormal situation that may be encountered in real-life situations. Examples of these situations include (1) a user being inattentive to the fitting of his earplugs, and (2) that proper training and motivation remain essential to successful implementation of hearing conservation programs.

REFERENCES

1. Canetto, P. and Voix, J. Hearing protectors "real world" performance and the European directive 2003/10/EC. Source Book, Workshop held at INRS Paris July 4th, (2008).

2. Berger, E. H., Voix, J., and Kieper, R. Methods of developing and validating a field-MIRE approach for measuring hearing protector attenuation, *Spectrum*, **24**(S1), (2007).

3. Voix, J. Mise au point d'un bouchon d'oreille "intelligent", Ph.d. thesis, École de Technologie Supérieure, Montréal, Canada (2006).

4. Voix, J. and Laville, F. Expandable earplug with smart custom fitting capabilities, Smart Hearing Protection, The 2002 Congress and Exposition on Noise Control Engineering, Dearborn, MI, USA. Available from InterNOISE, International Congresses on Noise Control Engineering, International Institute of Noise Control Engineering (I-INCE) Ames, IA, 833–841, (2002).

5. Voix, J. and Laville, F. The objective measurement of individual earplug field performance, *Journal of the Acoustical Society of America*, **125**(8), 3722–3732.

6. Berger, E. H., Voix, J., and Hager, L. D. Methods of fit testing hearing protectors, with representative field test data, Presented at the 9th Congress of the International Commission Biological Effects of Noise, Mashantucket, CT, July 21–25, (2008).

7. Voix, J. and Laville, F. Expandable earplug with smart custom fitting capabilities, Smart Hearing Protection, The 2002 Congress and Exposition on Noise Control Engineering, Dearborn, MI, USA. Available from InterNOISE, International Institute of Noise Control Engineering (I-INCE) Ames, IA, 833–841, (2002).

8. American National Standard, Methods for measuring the real-ear attenuation of hearing protector, ANSI, S12.6-2008 (2008).

9. Walpole, R. E., Myers, R. H., Myers, S. L., and Ye, K. *Probability and Statistics for Engineers and Scientists*, Prentice Hall, Upper Saddle River, NJ, 8th ed., (2007).