Methods of Developing and Validating a Field-MIRE Approach for Measuring Hearing Protector Attenuation

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TABLE OF CONTENTS

Introduction 1
Methods of field testing hearing protector attenuation 2
Field microphone-in-real-ear (F-MIRE) system 4
Protocol for validation of an F-MIRE system 5
Test facility and equipment 6
Test materials 6
Test subjects 6
Description of the experimental procedure 6
Results 8
Examination of the variability 10
Discussion 12
References 14

ABSTRACT

Numerous studies have shown that the reliability of using laboratory measurements to predict individual or even group hearing protector attenuation, for occupationally exposed workers, is quite poor. This makes it difficult to properly assign hearing protectors for critical high-noise environments, as well as for lower noise levels when one wishes to closely match attenuation to actual exposure. An alternative is the use of field measurement methods, a number of which have been proposed and are beginning to be implemented. We examine the pros and cons of the various techniques, review existing measurement devices and focus on the development and testing of a field microphone in real ear (F-MIRE) approach in which a dual-element microphone probe is used to measure noise reduction by quickly sampling the levels outside an earplug minus the levels inside, with appropriate adjustments to predict real ear attenuation at threshold (REAT). The method was tested on both foam and premolded earplugs by comparing conventional REAT results to F-MIRE data for the same fit of the device on 20 listeners under various conditions of fit and refit. We describe the accuracy and precision of the F-MIRE approach, and recommend how to develop uncertainty factors for application of the data.

INTRODUCTION

When properly and consistently worn, hearing protectors can effectively block noise and prevent hearing loss. That much is clear. However, the devil is in the details – how to train employees to wear their hearing protection devices (HPDs) properly, how to suitably assign HPDs commensurate with noise exposures, personal preferences, and anatomical considerations, and how to assure that employees wear them consistently. This takes care and awareness to detail, as well as individualized attention. Heretofore this was complicated by the fact that those dispensing hearing protection in industry had little or no training in how to fit hearing protection (Royster and Royster, 1999) and that the only noise attenuation data that were available were from group average data based on laboratory measurements as reflected in the Noise Reduction Rating (NRR). Even if the laboratory data were representative of the actual group using the device, the individual variability is large enough that attempts at predicting one person's performance from group data can easily err by up to 20 dB (Gauger and Berger, 2004).

One approach to solving these problems is the development of systems to allow individual fit testing in industry, and indeed such systems have been garnering increasing visibility in recent years. In fact, fit test technology has been available in the laboratory in many forms for nearly 30 years. Berger began publishing in this realm in 1984 (Berger, 1984; Berger, 1986; Berger 1988; Berger, 1989), but only in the past decade has the wider hearing conservation community started to look more closely at this issue. Recently, Berger (2006) discussed seven important applications for field-test methods, as listed below.

1) Train and motivate employees to properly and consistently wear their HPDs
2) Train the trainer on how to train employees
3) Assign HPDs based upon noise exposures and expected protection levels
4) Provide useful standard-threshold-shift (STS) follow up to see if the problem may be HPD related
5) May with time be accepted by OSHA as more accurate alternative to determine HPD adequacy
6) Audit departments to assess overall HPD effectiveness and suitability
7) Provide potentially useful documentation to defend against workers' compensation claims regarding HPD adequacy and provision of sufficient training

Today there are a number of systems that provide field-test capabilities, and one purpose of this report is to explore the various options with respect to their advantages and disadvantages. We will then focus on one of those methods, microphone in real ear (MIRE) and its implementation as a quick and portable field method, termed field-MIRE, abbreviated F-MIRE (Hager and Voix, 2006). We will consider how to validate and qualify an F-MIRE system, and how to provide an appropriate means of recognizing and addressing the inherent variability that is still present, even in field-test methods.

METHODS OF FIELD TESTING HEARING PROTECTOR ATTENUATION

Field test methods exist in three basic "flavors." They consist of subjective (psychoacoustic) methods, objective (microphone-in-real-ear), and non-acoustic (pressure and seal tests). The various methods are outlined below:

- Subjective (psychoacoustic)
  - REAT (real-ear attenuation at threshold)
    - Sound field (in a small booth or chamber)
    - Circumaural (with earphones in large noise-excluding cups)
    - Supra-aural (using standard audiometric earphones)
  - Loudness balance
- Objective [microphone-in-real-ear (MIRE)]
  - Probe microphone passed through or around an earplug
  - Microphones mounted inside and outside of earmuff cups
- Pressure / seal measurements (non-acoustic)

With the exception of the loudness-balance method, all of the subjective procedures are variants of the "gold standard," real-ear attenuation at threshold (REAT) procedure that is well documented in current and prior ANSI standards (ANSI S12.6). The intention is to replicate as closely as possible laboratory based REAT under field conditions. In the lab REAT requires listeners to track their hearing threshold levels much like when they take a conventional audiogram to measure their hearing sensitivity. The sounds are normally presented from loudspeakers in a test chamber and then the procedure is repeated, both with and without HPDs. The difference in the two thresholds is the attenuation of the device. This procedure is called real-ear attenuation at threshold since the attenuation of the HPD is computed from differences in the threshold of hearing, with and without the hearing protector in place (Berger, 2000).

To take REAT into the field, the loudspeaker presentation normally is replaced with a headphone presentation, i.e. speakers in large circumaural cups (or as noted above, sometimes mounted in standard audiometer earphone cushions), which enables testing of only earplugs. However, earplugs are the type of HPD that is most variable in fit and therefore most in need of fit testing. When the field procedure is accomplished using a small noise enclosure or sound booth, both earmuffs and earplugs can be evaluated, but with the additional cost and difficulty associated with positioning a booth near the workplace.

The advantage of field REAT is that it can yield valid data with only one known measurement artifact, namely that it produces values of attenuation that are spuriously high by typically up to a few decibels in the frequencies at and below 250 Hz. This is due to physiological noise masking in the occluded ear (Berger and Kerivan, 1983). The three field-REAT variants that are listed above have all been successfully implemented according to the literature, but the use of supra-aural earphones requires care due to potential artifacts (Berger, 1986).

A principal disadvantage of field REAT is its time-consuming nature. Each frequency tested takes at least 30 seconds, requiring a minimum of at least one minute to test the fit in each ear since both an open and an occluded threshold are required, much longer if multiple frequencies are to be tested. Furthermore, there is an inherent variability since the data rely on the listener's ability to track his or her own threshold. That process itself has a substantial imprecision of approximately ± 5 dB for typical subjects. Finally accurate REAT measurements require low background noise so that the open-ear thresholds are not masked and contaminated. Even when field REAT is conducted under large noise-excluding earmuff cups, or in a sound booth near the workplace, care must be exercised to be sure that the environment is adequately quiet.

The remaining subjective field procedure is that of loudness balance, recently updated with a new suggested paradigm (Soli et al., 2005). In this method, instead of comparing open and occluded thresholds, the subject is asked to establish a balance in the loudness between the ears using signals presented to unoccluded and occluded ears. Like a threshold procedure, this requires a listener's subjective response and the attendant time and potential variability, especially for untrained listeners as would be found in industry. Also, though the balance is probably not inherently any more difficult to track than a threshold, employees generally have some familiarity with threshold tracking because of the annual audiograms they receive as enrollees in a hearing conservation program. An advantage of loudness balance over REAT is that it is less susceptible to contamination from background noise since the loudness balances are conducted at sound levels that are normally at least 30 to 40 dB greater than in the REAT protocol.

An alternative to the subjective procedures is to make objective measurements with microphones, termed a microphone-in-real-ear (MIRE) technique (Berger, 1986). When applied in occupational settings this becomes a field MIRE (F-MIRE) methodology (Hager and Voix, 2006; Voix, 2006). With F-MIRE the sound pressure levels in the ear canal under the hearing protector, as well as 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, the values can be used to accurately estimate the hearing protector's attenuation.

MIRE can be conducted with probe measurement devices that consist of thin flexible tubes connected to microphones, with the tubes either placed in the ear canal or through the earplugs or between the earplugs and the canal walls. Working with the tubing can be tricky and can substantially affect the performance of the earplugs unless the tubing is sealed through the body of the plugs. The tubing itself can also leak sound through its wall if the material of the tube does not possess a sufficiently high insertion loss.

One embodiment of the F-MIRE system is Aearo Technologies' E-A-RFit™ system that is evaluated in this report. It incorporates a single small dual element microphone and associated proprietary technology (Voix and Laville, 2002 and 2004; Voix, 2006). 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. By using special probed versions of earplugs one can now test, in a matter of moments, the attenuation that is being obtained, regardless of the fit of the HPD that is being evaluated. The actual measurement takes about 10 seconds for any one fit in one ear to obtain data at the standard 7 test frequencies from 125 Hz to 8 kHz, as well as an overall noise reduction rating called the Personal Attenuation Rating (PAR[1]). The PAR, though it appears to be an exact number, also contains its own variability, albeit much less than in the classical approach of using mean laboratory data to make individual field predictions. The exact amount of variability in PAR is defined and explicitly provided with the measurement.

In addition to the brevity of the test, another advantage is that it can be conducted in substantially higher noise levels than can a field-REAT measurement, and it reduces the inherent variability by replacing the variance of the subject's open and occluded thresholds, or open and occluded loudness balances, with a smaller variance due to the measurement system. The system is excellent for training, monitoring, and other applications (Berger, 2006), but it does rely on surrogate HPDs that consist of earplugs modified by passing probe tubes through them. Thus the plug that the subject fits is not identical to the plug that will be worn on a day-to-day basis. This is discussed further in subsequent sections.

[1]The PAR is computed like a Noise Reduction Rating (NRR) except it is calculated individually for each subject and does not include either a standard-deviation correction or 3-dB spectral uncertainty factor.

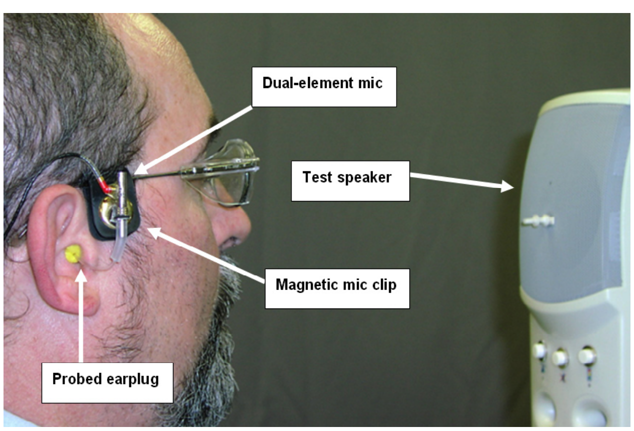
Another implementation of the MIRE approach is to instrument earmuff cups with internal and external microphones, as has been done for research purposes as well as the development of a product for regular use in industry to monitor hearing protector effectiveness (Berger, 1986; Burks and Michael, 2003).

The last type of field test method listed above is one based on pressure measurements (principally pneumatic) to determine the presence of an acoustic seal. This method has been primarily used to validate that a custom earmold is well made and fits the ear properly, and indeed it is suitable for such a purpose. However, translation of that seal to assurance of a particular degree of protection has sufficient uncertainty that this is not a viable method for field measurements except for possibly a pass/fail determination for selected types of products. This would not be a viable way to test most foam earplugs since, although they provide a strong acoustic barrier to sound, they do leak at very low frequencies, which is one of their positive attributes.

FIELD MICROPHONE-IN-REAL-EAR (F-MIRE) SYSTEM

Review of the preceding methods led to the determination that a MIRE approach provided the most effective means to conduct field measurements, yielding the best tradeoff between speed, accuracy, repeatability, and correspondence with actual practice. The F-MIRE method investigated in this study was adapted from one that had been developed by Sonomax Hearing Healthcare Inc. for use with their custom earmold technology (Voix and Laville, 2002; Voix, 2006). Certain features of the system required modification for use with a wide range of earplugs such as non-custom foam and premolded earplugs that provide high levels of attenuation, approaching the bone-conduction limits at some frequencies. The particular F-MIRE system evaluated in this study is the E-A-RFit™ system from Aearo Technologies.

Figure 1 illustrates the components of the system. Figure 2 provides an enlargement of the microphone and probed earplug tips. The F-MIRE system consists of a sound source that can generate high levels of broadband random noise at the listener's ear, a dual-element microphone that simultaneously measures in a repeatable location the sound present at the outside of the earplug and the sound present in the ear canal after having passed through the earplug, a probed earplug to act as a surrogate for the actual earplug that subjects will wear, and a robust analysis system installed on a desktop or laptop PC that can rapidly take accurate and repeatable measurements in typically 10 seconds. The sound levels used, depending upon the level of attenuation provided by the earplug, are up to 90 dBA. The listener's nose is positioned 30 cm from the front of the loudspeaker.



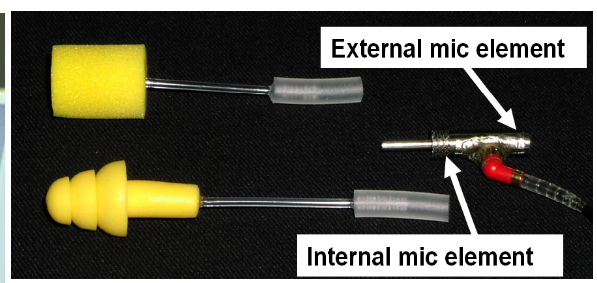


Figure 1 - *left* **- Key components of the F-MIRE**

Figure 2 - *above* **- The dual-microphone element and representative probed tips for foam and premolded earplugs.**

A key feature of the development of this F-MIRE system was the design of the probed test tips. The tubing through the plug must allow measurement via the dual-element mic of the sound pressure levels in the ear canal, but must at the same time have high levels of self-insertion loss (i.e., sound transmission through the wall of the tubing as opposed to sound transmission through the lumen of the tubing). The tubing must also be of sufficiently small diameter and adequate softness that it does not materially affect the listener's ability to insert the earplugs. In the case of the foam tips, the tubing also must not detract from the ability to roll the plug into a tiny crease-free cylinder for insertion into the ear canal.

PROTOCOL FOR VALIDATION OF AN F-MIRE SYSTEM

A properly designed and calibrated F-MIRE system can provide an excellent estimation of REAT. F-MIRE measurements yield what is termed noise reduction (NR), the difference between the levels outside and inside the ear canal. REAT, on the other hand, is an insertion loss (IL) measurement that indicates the difference in the levels at one point in space (namely the eardrum) with and without the HPD in place. NR and IL are directly related, but they are not the same; thus a mathematical adjustment is required that uses the transfer function of the open ear (TFOE), which is the difference between the sound pressure levels in the sound field and at the eardrum. See Berger (1986) for details. Besides the TFOE correction, sound conduction through the small lumen of the probe tube tips varies with frequency and this must also be accounted for. Other correction factors may also be needed (Voix, 2006).

The most direct way to account for all of the above factors is to make a simultaneous measurement of REAT and NR, for a given fitting of the probed earplugs on a group of subjects. One can then directly compare the measured values of attenuation and determine the best correction (also called compensation) factors to bring them into the closest possible agreement (Voix and Laville, 2002). This type of approach is commonly accepted and has previously been used for other types of field test systems (Michael et al., 1976).

The compensation factors noted above only describe the differences due to system bias, factors that are stable from measure to measure. There is also the question of the variability of the measurement systems and how those may differ. Accounting for this multiplicity of factors required the development of a complex test paradigm outlined in Figure 3, and discussed in detail below.

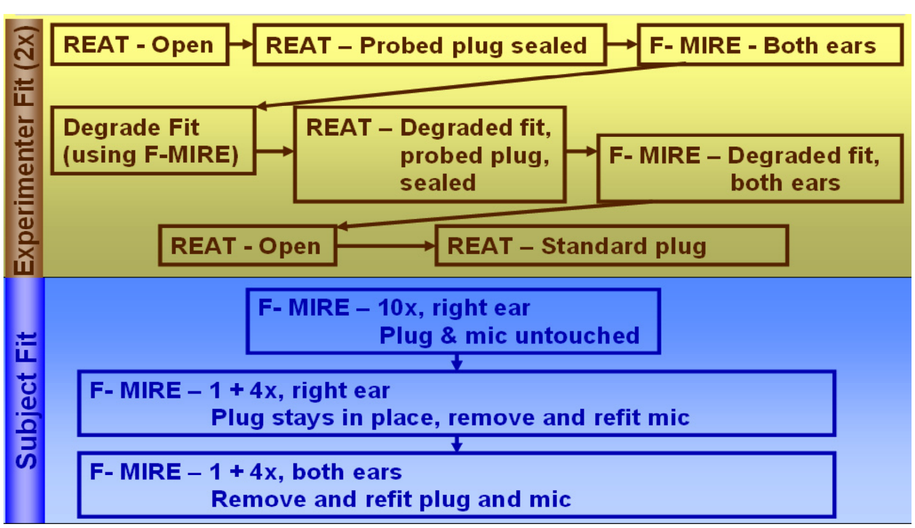


Figure 3 - Outline of experimental plan to determine compensation factors and measurement variability.

The figure is in two colors to highlight the two different parts of the protocol, the yellow section describing experimenter-fit tests designed to measure the compensation factors and the blue section describing subject-fit tests to assess the variability in the measurement procedure. Twenty experienced subjects on the E-A-RCAL^{SM} panel participated in the experiment for the evaluation of each probed plug. Each subject underwent the entire series of tests, approximately 90 – 120 min. of testing in a single session.

Test facility and equipment

The REAT tests were conducted in a 113-m^3 reverberant chamber with procedures in accordance with ANSI S12.6-1997. The facility is also accredited under the Department of Labor, National Voluntary Laboratory Accreditation Program for testing to the ANSI standard (Berger et al., 2006).

The E-A-RFit^{TM} system was described previously. The version of the software utilized in these laboratory experiments was 2.2.0. The F-MIRE measurements were conducted in the E-A-RCAL^{SM} laboratory immediately outside the test chamber. Sound levels were not controlled in that space, but neither were they critical for purposes of F-MIRE testing with the E-A-RFit^{TM} system. The background noise levels in the laboratory were representative of what might be encountered in a typical office or safety facility where field testing of HPDs might be conducted.

Test materials

In this first series of experiments, the goal was to develop compensation factors and evaluate the performance of the E-A-RFit^{TM} system and the accompanying probed plugs, also called “tips,” that are provided specifically for use with that system. The tips that were evaluated included probed versions of the Classic® and E-A-Rsoft® Yellow Neons® roll-down foam earplugs, the Push-Ins^{TM} pod plugs, the UltraFit® premolded earplugs, and the CustomE-A-R^{TM} custom earplugs. In this report, we focus on the data for the Classic, which are representative of the probed plugs tested thus far.

Test subjects

As has been discussed in the literature, test subjects and how the experimenter works with them are key to the results obtained in laboratory HPD attenuation measurements (Berger et al., 1998). Although the goal here was to obtain predictive results for field application of F-MIRE, we chose to work with the trained panel of E-A-RCAL^{SM} listeners. This was because Method-B type naïve subjects as described in the current ANSI REAT standard (ANSI, 1997) are not reliable enough in general to provide consistent results for the extensive testing required for these experiments. Moreover, with the amount of fitting, refitting, and controlled fitting necessary to get the desired levels of performance for development of predictive data over a wide range of attenuation values, naïve subjects would have quickly become experienced.

At a future date, time permitting, we may revisit the variability aspect of this experiment with a different group of subjects.

Description of the experimental procedure

Referring to Figure 3, each subject began with a REAT evaluation of a probed plug (open followed by an occluded threshold). For the occluded test, the plug was fit by the experimenter and the opening in the probe tube at its distal end was sealed with a brass plug. This provided a measurement of the attenuation of the probed plug that would reflect any flanking pathways through the walls of the tubing and the connecting sleeve. Thus, if the tube degraded the performance of the earplug itself, it would be apparent by comparing this measurement to that of an unadulterated (i.e. standard) earplug as discussed below.

The fit was controlled by the experimenter because the goal in this experiment was to obtain two distinctly different fits of the plug for each subject in order to obtain a measure of the correspondence between the REAT and F-MIRE data over as wide a range of attenuation values as possible. Since our goal was not related to evaluating a subject's ability to fit the product, the fact that the experimenter inserted the plug was not an issue.

At the high end of performance, we obtained as good and deep a fit as possible, similar to what would be achieved during an Environmental Protection Agency (EPA compliant) product labeling test. (See Figure 4.) At the low end of attenuation, the fitting for the degraded condition of fit discussed below, we purposely reduced the quality of the fit, but did not totally corrupt the performance, since the intent was to measure the poorest protection for which one might wish to use a fit-testing system. In cases where the plug's fit was so dreadful as to be visually apparent to all but the most unobservant or untrained fitter, it is unlikely that the use of a fit testing device would be attempted. Even if it were, the positioning of the plug would be so unstable in the ear that it would be impossible to take a reliable reading.

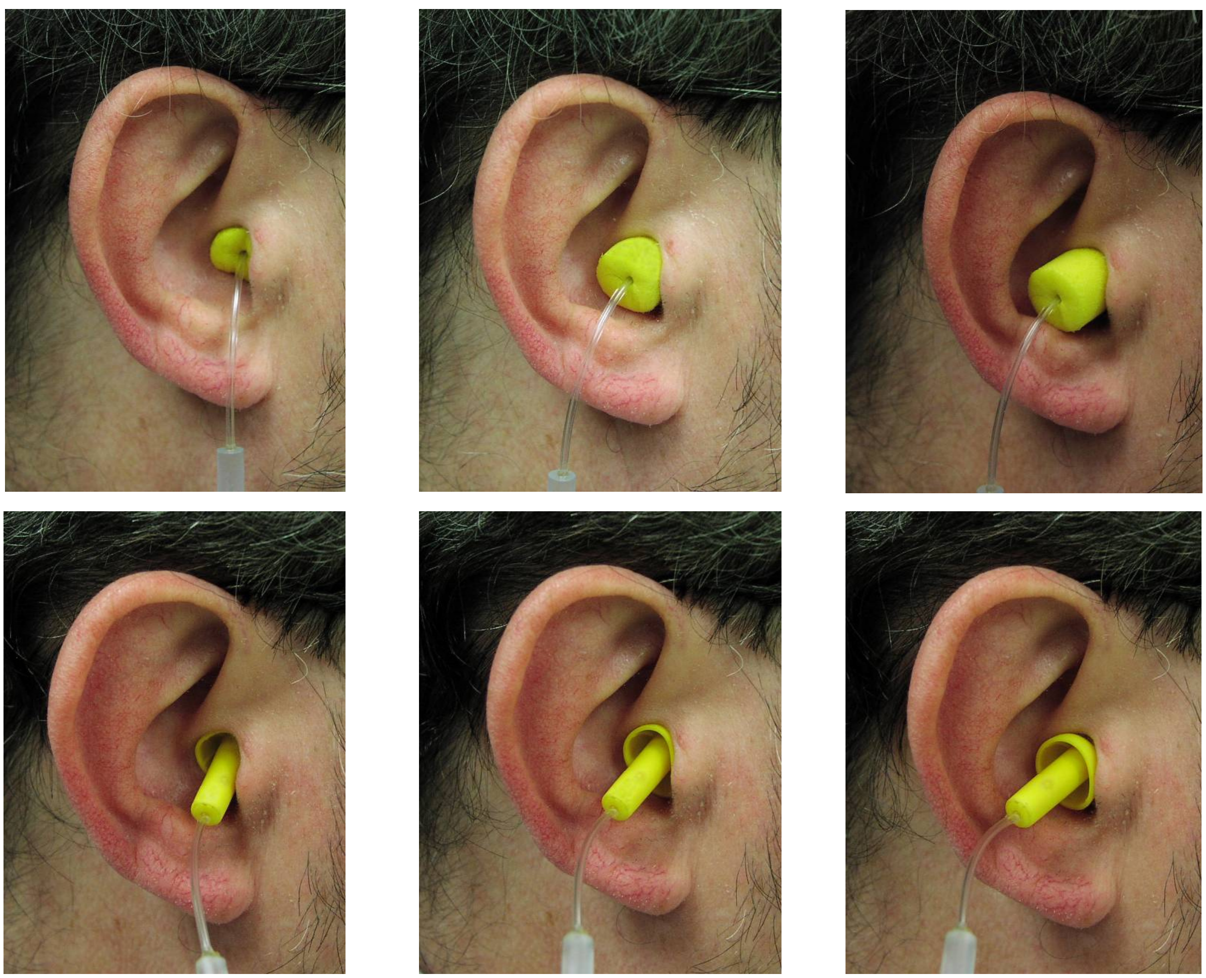


Figure 4: Examples from left to right of good, degraded, and unacceptable fits for the probed Classic® foam earplugs and UltraFit® premolded earplugs used in the F-MIRE testing procedure.

Following the REAT, the subject exited the chamber, the F-MIRE microphone was plugged into the probed plug, and objective attenuation measurements were taken for both ears. This first set of "paired" measurements provided the comparison between REAT and F-MIRE for a well-fitted earplug.

The plug's performance was then degraded and repeated F-MIRE values were recorded until the desired level of reduced attenuation was achieved. This varied by product, approximately 10 – 25 dB for roll-down foam earplugs, including the Classic and Neon, and 10 – 15 dB for premolded earplugs, including the UltraFit. Once a desired fit was obtained, the last F-MIRE value was retained for documentation, but not used in the subsequent analyses. The microphone was removed from the plug, being as careful as possible not to dislodge the less-than-ideally seated earplug; the brass nipple was re-inserted, and the subject then entered the chamber for an occluded test of the degraded fit. Immediately thereafter, the subject exited the chamber for an F-MIRE test on the same fitting.

The second F-MIRE test, post-REAT testing, was used for comparison to the REAT data. The reason for selecting the second F-MIRE test was that this would conform most closely to actual field experience, in that subjects would fit plugs to their ears and then use the F-MIRE to find out how they did. An additional justification was that we were less likely to affect the fit of the poorly seated plug during insertion of the probe mic than during its removal, when we had to be careful not to tug on the plug and degrade its fit further, prior to the REAT evaluation. After the second F-MIRE test, the subject re-entered the chamber for a REAT evaluation (open and occluded threshold) on a well-fitted unadulterated (i.e. standard) earplug. The purpose of the last test was to assess the amount by which the attenuation provided by the fully sealed probed plug might fall short of a standard plug by virtue of having placed a tube through the product. The entire sequence described thus far was repeated a second time. That concluded the portion of the test sequence shown in yellow in Figure 3.

The remaining testing was accomplished immediately outside the test chamber, in the E-A-RCAL℠ laboratory (see Figure 3, blue section). This consisted of repeat F-MIRE measurements to assess the reliability of a subject's insertion of the probed plug and the inherent repeatability of the F-MIRE testing system. We began with 10 repeat measurements of a subject-fitted earplug in the right ear. Nothing was touched between these 10 measures, so this provided an indicator of the inherent repeatability of the F-MIRE hardware and software. The last of the 10 measurements was then retained and used as the first of five measurements wherein the mic was removed and replaced into the probed plug[2]. This yielded a measure of the variability of the F-MIRE hardware and software together with the variance caused by fitting the microphone.

Finally, to get a measure of the variability of the subject's fitting of the earplugs, the last of the prior right ear fittings was retained, and then a left-ear measurement was also conducted. Then the plug was removed and refitted four additional times, for a total of five repeat measures on a removed and replaced earplug. This concluded the full series of tests on a single subject.

[2]This portion of the protocol was devised after the experiment had already concluded on the Classic and UltraFit earplugs and was only added for subsequent probes that were evaluated.

RESULTS

As previously discussed, the experimental paradigm has thus far been completed on five different probed earplugs. This report will examine the data for only the probed Classic foam earplug. The results are in large part representative of the other tips tested, and furthermore, since the Classic gives values of attenuation approximately as high as any type of earplug that an F-MIRE system might evaluate, it provides a thorough test of the dynamic range of the measurement system.

Before we can compare the basic REAT and F-MIRE data, the question arises regarding how to compare binaural REAT data (in that paradigm both ears are measured simultaneously) and F-MIRE data wherein each ear is measured separately. The approach used herein was to consider that the ear that dominates in the REAT test is the one controlling the result. The dominant ear will be the one perceiving the highest sound levels and that will be controlled by the ear at each frequency that has the least attenuation offset by any differences, ear to ear, in the absolute threshold. This is mathematically developed and presented by Voix (2006). Although throughout this section we use this method to generate equivalent binaural data from the individual-ear F-MIRE results, in practice, when such a system is used for testing fit of HPDs and for training, the immediate feedback to the subject will be provided one ear at a time.

Figure 5 presents the basic REAT validation data for the probed plugs. In it we compare the results from a standard experimenter-fit labeling test on the Classic foam plug (10 subjects tested 3 times each), to the values obtained in this study on 20 subjects for a standard unmodified plug, and also to the probed plug sealed with a brass nipple. The key comparison in this study is between the probed plug and the standard plug. The values are close indeed, differing only by about 3.5 dB at 125 and 500 Hz, and agreeing more closely at the other five test frequencies. This demonstrates that the tube does not create substantial flanking pathways, and that the plug can still be properly rolled and inserted regardless of the presence of the tube in the plug. The remaining curve in the chart indicates the attenuation for the purposely degraded fit of the product, showing that we achieved the goal of a substantially different performance characteristic than found for a well-fitted plug.

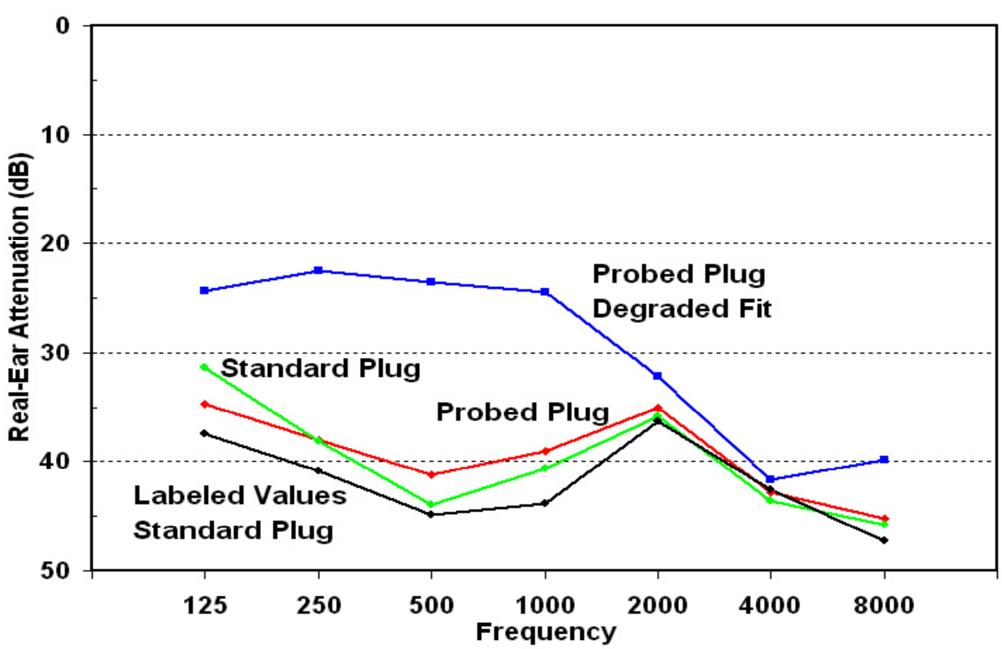


Figure 5 - Validation of the attenuation of the Classic probed plug tips by comparing REAT data for a standard unmodified plug to published test data (labeled values) and to probed plugs in this study (N = 20 subjects).

Figure 6 presents the averaged trends for the REAT vs. F-MIRE results that establish the validity of using the compensation factors from this study to make predictions of REAT data from a MIRE measurement. We have separated the data by well-fitted and degraded-fit insertions. The solid lines are the REAT values and the dashed lines the F-MIRE values with the compensation included. There was a difference in the optimum compensation factors depending upon the quality of the fit. With the factors adjusted for the good-fit data, there was an under prediction at 125 Hz and from 2000 to 4000 Hz for the degraded-fit data. This occurs at 125 Hz because there is a larger occlusion effect for a more shallow fit of the earplug and thus a larger spurious increase in the REAT values due to physiological noise-masking errors (Berger and Kerivan, 1983). At the higher frequencies, the differences may be attributed to volume- and tube-length corrections that change with frequency. The selected compensation factors were computed from the entire set of data, but adjusted so that the average over-prediction of the REAT values for the good-fit data never exceeded 2 dB.

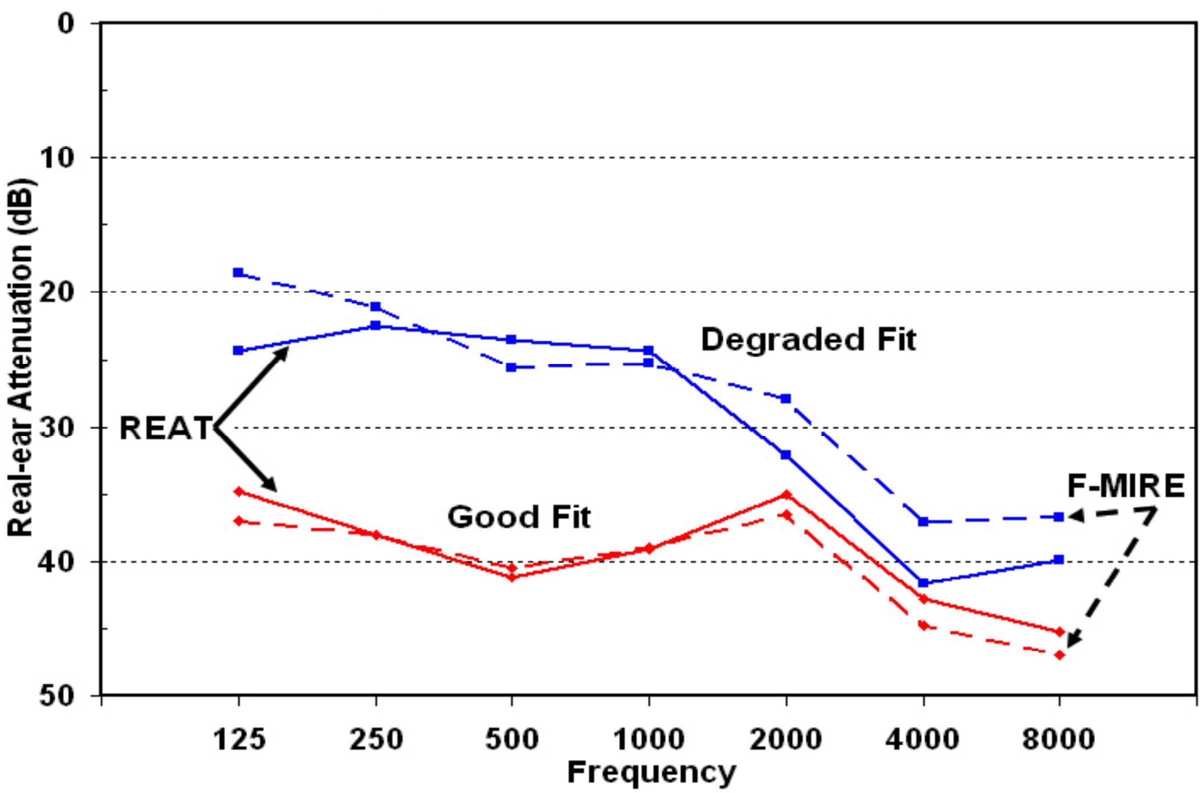


Figure 6 - Comparison of corrected F-MIRE predictions, using compensation factors determined in this study, to REAT data for the same fit for 20 subjects.

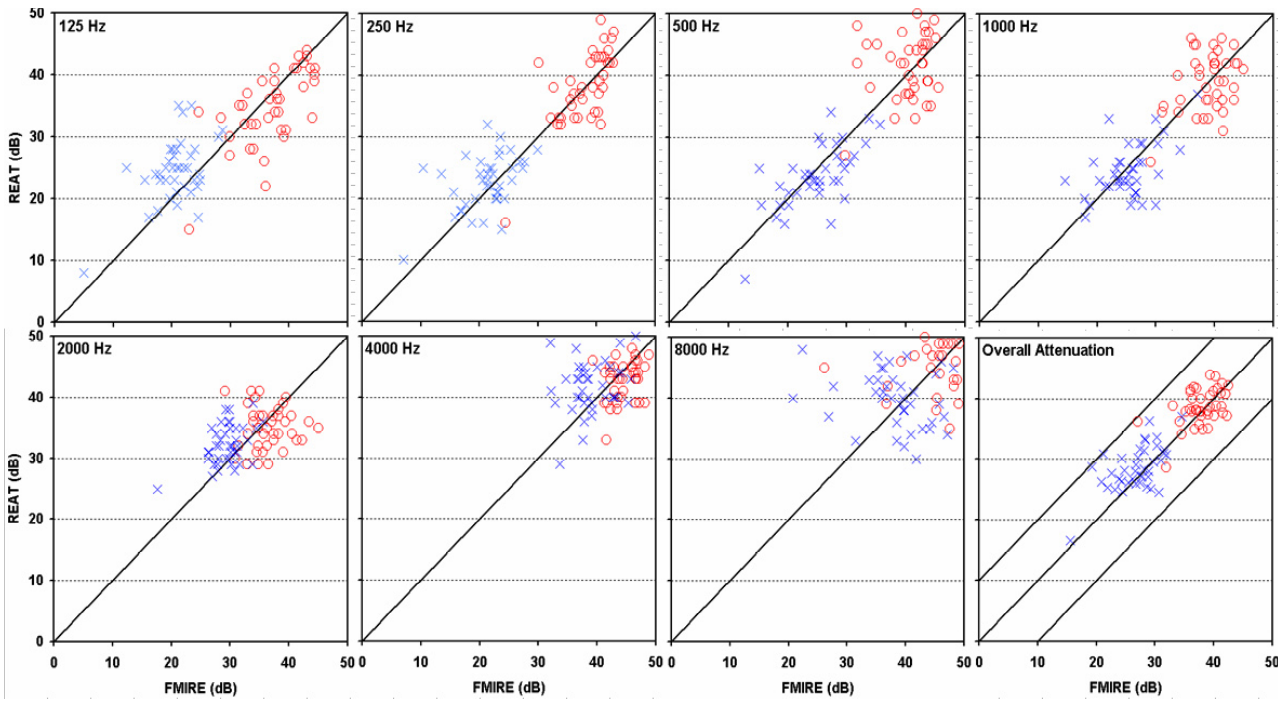


Figure 7 - Scatter plots of the REAT vs. F-MIRE predictions for two conditions of fit for seven 1/3-octave-band test frequencies and for an overall PAR (N=20 subjects). Diagonal lines represent 1-to-1 relationship; in lower right panel additional lines are at ± 10 dB.

An alterative view of the data is provided, frequency-by-frequency, in Figure 7, in terms of scatter plots with the measured F-MIRE values on the horizontal axis and REAT plotted on the vertical axis. The good-fit values are shown in red and the degraded fit in blue. The data are presented for the seven 1/3-octave-band test frequencies as well as an overall attenuation value, the PAR. Superimposed on the data is a one to one correlation line, as well as ± 10 dB error bars (overall data, lowermost right panel only) to indicate points for which the prediction from the F-MIRE values would be in error by greater than 10 dB. The compensation factors in the F-MIRE data have been adjusted for best fit. Ideally, the agreement between the F-MIRE and REAT should be independent of the level of the attenuation, but examination of the charts indicates that this is not strictly true at some frequencies, such as 125 Hz and 4000 Hz. The trendline is a closer fit for the red values than for the blue. The compensation was adjusted for best overall fit with the proviso, as previously stated, that on the average no F-MIRE prediction was allowed to exceed the REAT by greater than 2 dB.

The uncertainty (standard deviation) of the predictions ranges from 4.6 dB to 5.6 dB for the frequencies from 125 Hz to 4 kHz, increasing to 7.7 dB at 8 kHz. At that high frequency, with its shorter wavelengths, the compensation factors have more variability and thus there is less reliability in those F-MIRE predictions. Looking at the scatter plot for the prediction of the overall REAT from the PARs, the spread is substantially tighter with an uncertainty of 3.3 dB. Indeed, this is how such data would most often be utilized in terms of a single-number reduction factor.

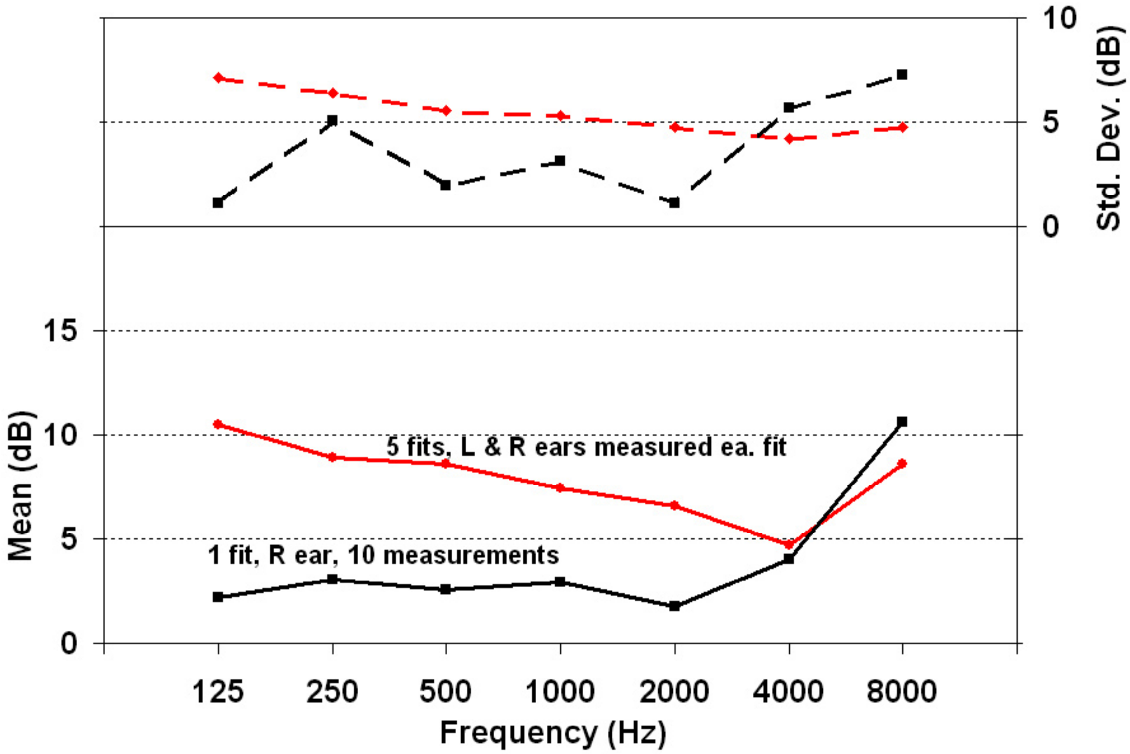


Figure 8 - Comparison of inherent variability of the F-MIRE measurement system (repeat measurements on 1 fit of plug) to the total variability (multiple fits of plug with test mic removed and replaced each time). Value plotted is the mean and standard deviation of the range across repeat measurements on 18 subjects (missing data for 2 of 20 subjects).

EXAMINATION OF THE VARIABILITY

The results in the preceding section indicate that on the average, the F-MIRE predictions are reliable indicators of the actual REAT values. However, review of the scatter plots indicates that errors for a single measurement on one individual can exceed 10 dB. To understand the sources of those errors, we included a number of repeat measurements in the test protocol.

In Figure 8, we compare the variability for 10 repeat measurements for a single fitting of the Classic foam (i.e., nothing is touched, we just press the run button and take the measurement 10 times) to the variability for five separate measurements for both ears in which the mic is removed from the plug, the plug is removed from the ear, and the subject refits the plug and the experimenter refits the mic. In this portion of the experiment, the fitting is done by the subject and not by the experimenter. The lower part of the chart presents the mean of the range of values for each subject (i.e. maximum value minus minimum value) at each frequency for both sets of measurements. The upper part of the chart shows the standard deviation of the ranges. For repeat measures (same fit) the range is from about 2 – 4 dB at all frequencies except 8 kHz where it increases to 11 dB. For the refit condition the variability is from 3 to 4 times larger at most frequencies except 4 and 8 kHz. The conclusion is that the largest part of the measurement problem is the precision with which the subject can fit and refit the plug.

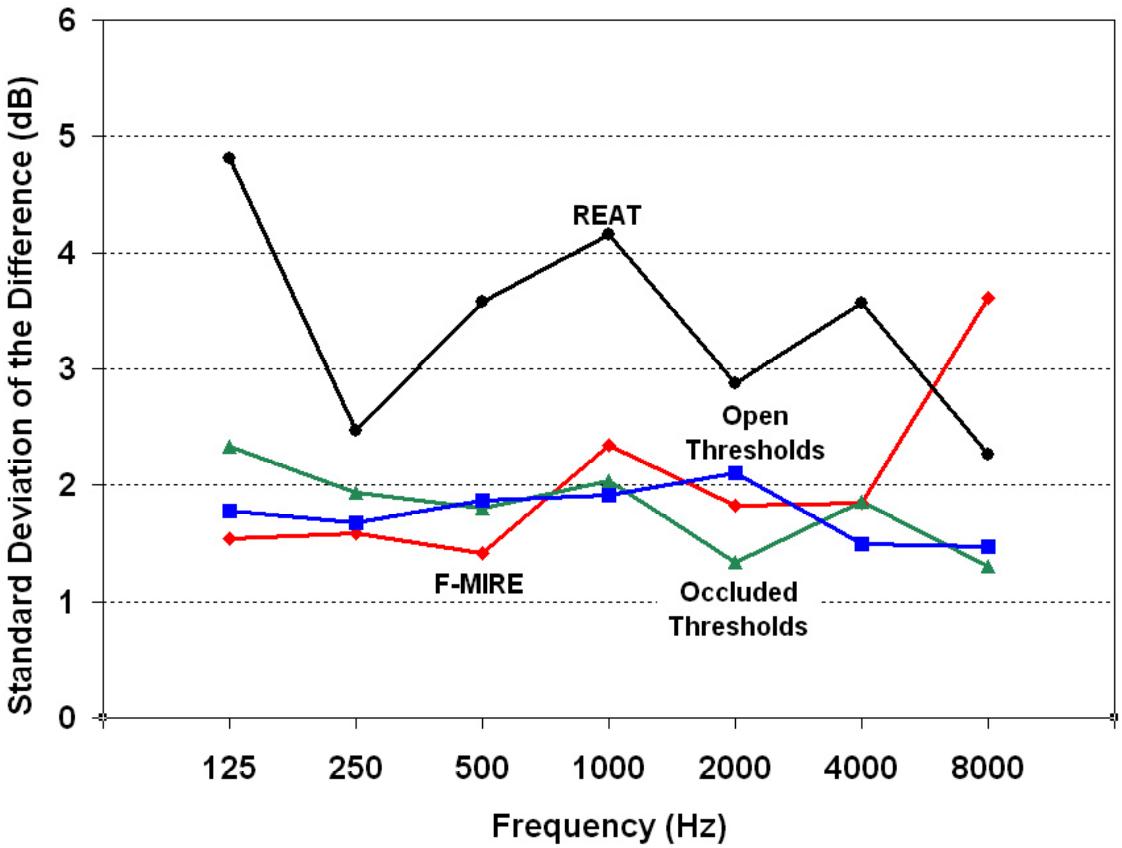


Figure 9 - Comparison of variability of F-MIRE measurements to open and occluded threshold measurements and to REAT data based on 13 subjects, two measurements each. The open threshold data are from a prior experiment on a similar group of subjects, and reflects typical open threshold variability found in this lab.

Another question to address is what might happen if field fit testing was accomplished with a field REAT approach, as opposed to F-MIRE. Figure 9 presents relevant data from a pilot study that preceded the experiments reported herein, but with essentially the same paradigm. However, added into those experiments was a repeat occluded threshold for the same fitting of the plug at the end of each series, so that we captured multiple opens and two occluded thresholds in order to compute variability data.

The red line in Figure 9 shows the measurement variability for two repeat F-MIRE measurements on 13 subjects with everything held constant, i.e. one fitting of the plug with the probe mic attached. Unlike Figure 8, in which are presented statistics computed for the range in values experienced by each subject across 10 measurements, evaluated across subjects, Figure 9 instead provides the standard deviation of the differences for each subject between their two thresholds. The green line in Figure 9 depicts the variability of the repeat occluded thresholds (on the same fit of the plug). The variability is similar to that found using F-MIRE. However, since REAT is a difference between two thresholds, the most appropriate curve to which to compare the F-MIRE variability is the black line (REAT values) that includes the square root of the sum of the squares of the variances of both the open and occluded thresholds. Those values, except at 8 kHz, are substantially greater than the variability of the F-MIRE system.

DISCUSSION

In developing and validating an F-MIRE approach a number of factors must be taken into account as discussed in this paper. These include the design of the probe tips such that use of the probed product closely mimics use of the standard unmodified earplugs, the accuracy and precision of the measurement system, specification of system and measurement variability, and guidance for the end user on the meaning of the results. The work in this paper has addressed the first two topics; subsequent papers will examine these issues in greater detail and also address the remaining topics. Unusual features of this work were not only the unique character of the F-MIRE system that was devised, but also the comprehensive test protocol that was utilized to examine numerous aspects of both the development of compensation factors and the variability of those factors when used in realistic predictions.

It was shown that compensation factors could be developed for the F-MIRE probe system that permit prediction of "true" attenuation (as measured by the standard REAT protocol) with an overall uncertainty of about 3.3 dB. Though data were only presented in this paper for a probed Classic earplug, experience with other types of probed products has demonstrated uncertainties from about 2 to 4.5 dB. However, as shown in Figure 8, the principal portion of the uncertainty is the fitting repeatability and thus, in practice, the uncertainty can be addressed by recommending or requiring additional fittings on an employee to gain a more precise prediction. This would serve the added benefit of providing additional practice for the employee to enhance the likelihood of the individual obtaining adequate protection independent of any concerns regarding the prediction of that protection.

A factor not fully accounted for herein is validation of the measurement uncertainty with actual untrained employees in a hearing conservation program, or with subjects meeting the requirements of the Method B protocol of ANSI S12.6-1997. That was not feasible in this protocol because of the requirements for subject retention and regardless, the requirements for naïveté would have been abrogated by the multiple retests needed in this study. At a future time, we envision testing uncertainty in the field with a revised protocol.

An important issue in designing probes was to assure for the foam plugs that the tubing was sufficiently narrow and soft that it did not affect the ability to roll down the product for proper insertion. The probes that were developed were found to be quite usable in our experiments. It is unclear however if the tubing would affect the ability of inexperienced subjects to properly insert the plug. We hope to test that in a Method-B protocol by comparing the REAT values for inexperienced users inserting sealed-tubed plugs and unmodified plugs. However, if the tubing is found to be a problem, it is most likely a "safe" error that would interfere with the ability to insert the plugs. Thus, if the subject can obtain adequate F-MIRE measured protection with the tubed product, s/he will certainly do so with the unmodified plug as well.

As the F-MIRE process is refined and brought to actual field application, guidance will be provided on the degree of uncertainty and how it varies with repeat measurements. This will be application specific and level dependent. For example, to assign an HPD to a particular high level noise based on its octave-band spectrum would require repeat measurements to reduce the uncertainty and make the process worthwhile. On the other hand, in a relatively low-level noise environment with time-weighted average exposures in and around 90 dBA, the precision required in an attenuation estimate would be much less.

Meanwhile, the hearing conservationist now has available a portable, convenient, quick and easy-to-use system that can be implemented in programs to improve training and motivation of employees, and to address other management and compliance issues.

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