State of the Art Hearing Protection with Custom HPDs
SafetyMeter Fit Testing System Confirms Superior Performance

Summary

It is well known that universal fit ear protectors like foam plugs often struggle to provide sufficient hearing protection in the field and that their in-ear noise reduction is much less than the declared attenuation values. 'First time good' protection can be as low as 59% for universal plugs. A detailed analysis of Phonak eShells (custom-molded ear plugs), shows that 96% of users get 'first time good' protection, rising further to 100% when these eShells are tested with Phonak SafetyMeter fit testing software. It can be concluded therefore that Phonak eShells are a much safer hearing protection solution than universal plugs.

Introduction

It is widely accepted that published hearing protection attenuation ratings such as SNR (Single Number Rating) and NRR (Noise Reduction Rating) do not reflect the attenuation a person will obtain when using the same protector in real life. Published attenuation data for hearing protectors are based on average values obtained for a group of users (under ‘optimized’ fitting) during laboratory tests. The real life attenuation provided by standard ear plugs depends on the correctness of their fit, i.e. the ability of the end-user to correctly position the protection in the ear canal and choose the appropriate sized protection. The percentage of universal plug users who receive the right protection the first time they attempt to use their product has been reported by Hager to be as low as just 59%. After retraining, an additional 25% of users were able to insert their hearing protectors correctly into their ears.16% however needed to switch to alternative hearing protecting.

The attenuation provided by custom molded plugs depends on the quality of the impression, the accuracy of the manufacturing process, and correct insertion in the ear.

To account for the difference between laboratory and real-life attenuation values, de-rating factors are used in several countries based on recommendations by local regulatory agencies.

In the USA for example the National Institute for Occupational Health and Safety (NIOSH) has defined the following de-rating factors:

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<th>De-rating of formable plugs</th>
<th>50% off labeled NRR</th>
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<tbody>
<tr>
<td>De-rating of custom plugs</td>
<td>50% off labeled NRR</td>
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In Germany the Deutsche Gesetzliche Unfallversicherung (DGUV) has defined other de-rating factors:

<table>
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<th>De-rating of standard plugs</th>
<th>9dB off labeled SNR (formable plugs)</th>
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<tbody>
<tr>
<td>De-rating of custom plugs</td>
<td>3dB off labeled SNR (premolded plugs)</td>
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In addition, in Germany fit testing is mandatory for custom-made hearing protection devices. The difference between the American and German regulations is remarkable: custom plugs with a labeled NRR/SNR of 30 dB are de-rated by 15 dB in the USA and by 3 dB in Germany.

To investigate the effectiveness of custom plugs, tests were performed to measure the in-field attenuation with Phonak custom molded hearing protection plugs, called eShells. With universal protection like foam plugs performing so poorly, it was important to determine whether custom plugs might be a viable, more effective alternative.

At the same time, not all custom plugs are the same, as the production process plays an important role in the quality of any final custom products. Phonak's eShells are manufactured according to a strict best practice process with quality controls at each step, as described in Figure 1. Therefore the results and conclusions for Phonak eShells can not be applied to custom-made hearing protectors in general.

Materials and Methods

From January 2011 to October 2011 (10 months) 2,068 Phonak eShells (1,034 pairs for 1,034 users) were tested using SafetyMeter, Phonak's proprietary fit testing system. Phonak eShells are custom made full-concha ear plugs. Testing was carried out at 29 different industrial locations by ten different SafetyMeter operators. All users received basic hearing protection fit training from the SafetyMeter operator. Their insertion of the eShells was then carried out without any assistance.

Phonak eShell manufacturing

The manufacturing process of Phonak eShells is a state-of-the-art production. It starts with a technician taking impressions of both of a user's ears. A 3D laser scanner then digitizes these impressions with micrometer precision, and the data are stored electronically to ensure no loss of quality. These digital scan data are then fed into Digital Modeling...
Software, which defines the precise sealing and retention areas required. In pressure-sensitive parts of the ear, the size of the eShell might be reduced, while in less-sensitive ‘retention’ areas (where an eShell’s fit is secured) the size may be enlarged to ensure optimal sealing of the ear canal. Finally, the eShells are produced using a Selective Laser Sintering (SLS) production process which forms the eShells, layer-by-layer in 0.1 mm steps, from clinical nylon powder, which is melted using a CO\textsuperscript{2} laser.

![Figure 1. Manufacturing process of Phonak eShells. Each diamond (○) represents a quality control that needs to be passed before the next production step can be taken.](image)

The result of this process is a highly comfortable and fully biocompatible custom-made eShell (see Figure 2) that stays perfectly in the ear without causing irritation. Different acoustic filters can be placed inside the eShells to supply different levels of attenuation as required by the user. The manufacturing process’ different quality controls are as follows:

1. Only well trained, certified professionals are permitted to take ear impressions.
2. Before an ear impression is scanned, a thorough visual inspection is carried out by a technician. Any inferior quality impressions are rejected and new impressions are taken.
3. The scanning operator checks the laser scan of the impression. Only accurate scans make it to the modeling process.
4. The modeling operator checks that the ear geometry can be modeled.
5. The modeling operator checks the digitally modeled eShells before they go into production.
6. The Selective Laser Sintering production machine operator sets the machine’s parameter settings.
7. The operator also checks the dimensions of ‘control parts’. (In each production batch some shapes are manufactured with standard dimensions and tolerances). If these control parts are not within specified tolerances the full batch is rejected.
8. A final visual eShell check is performed before delivery to the client.

Figure 2: Phonak eShells: state-of-the-art custom-molded hearing protection plugs

Phonak SafetyMeter – proprietary fit testing system

SafetyMeter is a computer-based F-MIRE (Field Microphone-in-Real-Ear) fit testing procedure that is performed under special headphones. With SafetyMeter sound pressure levels outside and inside the ear are measured in octave bands. Testing is carried out simultaneously for both ears. SafetyMeter is an objective acoustic test and testing time is about 20 seconds. The full SafetyMeter test sequence, including training of the user and data logging, takes approximately five minutes. SafetyMeter computes the PAR – Personal Attenuation Rating – of an individual user’s personal eShells. The software has built-in coefficients matched to predict the SNR (Single Number Rating), the European equivalent of the American NRR. Each ear shell is then individually accepted or rejected. SafetyMeter rejects badly fitting eShells according to built-in acceptance limits. Safety Meter results are a Key Performance Indicator (KPI) of the Phonak eShell manufacturing process. Continuous analysis of all test data allows a technician to track the origins of any errors and implement corrective action.

Results

Testing with SafetyMeter was carried out with one of two different filters (white or brown). For 534 eShells with the white filter the mean measured PAR was 32.4 dB, with a standard deviation of 3.7 dB (see Figure 4). The published SNR (based on laboratory measurements, mean minus one standard deviation) is 29 dB.

Figure 4. Distribution of PAR values as measured with Phonak SafetyMeter in the field. N = 534. For the white filter the mean PAR is 32.4 ± 3.7 dB.

For 1,534 eShells with the brown filter the mean measured PAR was 28.7 dB, with a standard deviation of 3.8 dB. The published SNR (based on laboratory measurements, mean minus one standard deviation) is 25 dB.
The difference between the mean SafetyMeter PAR minus one standard deviation versus the published SNR is shown in Figure 5.

![Figure 5. The SafetyMeter data collected in the field (red bars show the mean Personal Attenuation Rating minus one standard deviation) are very similar to laboratory data (the SNR, which is the mean attenuation minus one standard deviation). This is true for both type of eShell filter: white and brown.](image)

Of all first-time Phonak eShell users tested with SafetyMeter 96% achieved ‘first time good’ hearing protection. All eShells that did not fit tightly were rejected and replaced. As a result, after SafetyMeter testing 100% of users were found to receive ‘good’ hearing protection.

**Discussion and Conclusions**

It is clear that not all custom plugs perform equally. This study investigated Phonak eShells, produced in a state of the art production process with multiple quality controls at each production step and a feedback loop from SafetyMeter fit testing into the production chain to optimize production accuracy and hence safety of Phonak eShell users.

Only 4% of all eShells did not fit perfectly upon delivery, meaning that from the very first fit 96% of Phonak eShells provide protection. Well-designed and accurately manufactured custom plugs such as Phonak eShells provide a much better attenuation than standard plugs. After SafetyMeter verification, 100% of eShell users achieved ‘good’ protection.

We can also assert that the SafetyMeter PAR is a highly accurate predictor of the SNR and the standard deviation of the SafetyMeter PAR is less than 4dB. As such, fit testing using Phonak SafetyMeter takes the guess-work out of hearing protection device fitting.

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