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Market surveillance of custom-moulded earplugs

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Market surveillance of custom-moulded earplugs

Emma Shanks BSc MIOA
Jacqueline Patel BSc MSc MPhil MIOA
Health and Safety Laboratory
Harpur Hill
Buxton
Derbyshire
SK17 9JN

Earplugs are available that are custom-moulded to the shape of an individual's ears. Such earplugs when used as personal protective equipment in the workplace can offer a longer life span, potential cost savings to employers and, it is often claimed, an improved level of protection and comfort compared to other forms of hearing protection. A study of a selection of CE-marked custom-moulded earplugs available in the UK was carried out in order to examine the protection provided by such devices, and to identify any influencing factors on protection, comfort and fit.

Five models of earplug were subjectively tested using either six or seven subjects. Apart from one poorly performing self-moulded earplug, the plugs provided attenuation (SNR values) in the range 16 to 24 decibels. Levels of protection for all plugs were lower than indicated by manufacturers, and statistical analysis suggested that three of the earplug models were not adequately represented by the manufacturer's attenuation data. There was no evidence to support the view that custom-moulded earplugs provide improved levels of protection compared to other forms of hearing protection. When checked against the labelling and information requirements of the relevant product standard, BS EN 352-2:2002, only one of the models completely satisfied the requirements of the standard. A variety of information was missing including attenuation data and fitting instructions.

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EXECUTIVE SUMMARY

Objectives

Under the Personal Protective Equipment Regulations 2002, requirements are set out which relate to the placing of personal protective equipment on the market. Custom-moulded earplugs fall under these Regulations. Custom-moulded earplugs are becoming increasingly popular as an alternative choice to earmuffs or other forms of earplug as they can offer a longer life span, potential cost saving benefits to employers and a guaranteed fit every time they are used as they fit only the wearer for whom they were made. Impression taking and moulding can influence the comfort and fit of the final product and the protection afforded.

The objectives of this study were to:

1. Measure the sound attenuation of a sample of CE-marked custom-moulded earplugs using a subjective method of measurement;

2. Compare the measured attenuation with the attenuation data provided by the manufacturer;

3. Identify factors that may account for any discrepancies between the manufacturer's attenuation data and the measured attenuation.

The results of the study will be used to inform HSE's position on custom-moulded earplugs, and the advice it gives to employers and employees on this type of personal hearing protection.

Main Findings

For all the custom-moulded earplugs tested, the average measured attenuation values were less than the manufacturer's values in all frequency bands, with the exception of two earplugs: one where measured values were slightly higher in the 2 kHz and 4 kHz frequency bands and one where the measured values were slightly higher in the 4 kHz band only. Consequently, the mean single number attenuation values (H, M, L and SNR) based on the measured attenuation values were lower than the manufacturer's values.

The mean SNR values calculated from all the measured attenuation values were between 0.5 dB and 10.2 dB lower than the values provided by the manufacturers, indicating that the in-use noise level perceived by the wearer of the earplugs would be between a factor of 1 and 10 times higher than would be assumed. However the mean SNR values based on the measured attenuation for the earplugs produced by the manufacturers/suppliers (i.e. excluding a self-moulded variety with a poor performance) were between 16.5 dB and 23.7 dB, indicating that they provided some protection to the wearer.

The measured attenuation values for only one earplug satisfied the minimum attenuation requirement of BS EN 352-2:2002 in all frequency bands. The measured attenuation values for one earplug were less than the minimum attenuation requirement in six out of seven frequency bands, and gave negligible attenuation below 2 kHz. This earplug was the type designed to be moulded by the wearer.

Statistical analysis showed that two of the five earplugs gave measured attenuation values that were in general not significantly different from the manufacturer's values. However the remaining earplugs had measured attenuation values that were significantly different across all, or all but one, of the frequency bands. This indicates that for these three models, the earplugs being supplied are not represented by the attenuation data supplied with them.

The very poor performance of the earplug designed to be moulded by the user, indicates that the making of a custom-moulded earplug based on precise impressions of the user's ears should not be left to untrained individuals; it requires skill and training.

Only one earplug met all of the relevant requirements specified by BS EN 352-2:2002. A variety of information was missing for all the other earplugs tested including attenuation data, fitting instructions, advice to fit, adjust and maintain in accordance with manufacturer's instructions, advice to regularly inspect, and recommended storage conditions. The absence of some of this information could have a detrimental effect on the performance and life span of the earplug.

There appeared to be no correlation between comfort and attenuation. Subject comments suggested that comfort could be rated according to the characteristics of the material from which the earplug is made and a good fit. However there are too few subject comments to say for certain whether or not these factors are important in relation to the comfort of custom-moulded earplugs.

The measured attenuation values correctly identified the custom-moulded earplug with the flat response. Although the other earplug models were either vented or solid custom-moulded earplugs, the attenuation characteristics based on the measured data were comparable, i.e. relatively low or negligible attenuation up to and including 1 kHz and then higher attenuation at higher frequencies. This response is generally typical of a vented earplug.

Recommendations

It is important to note that the recommendations given here are based on both a small sample of custom-moulded earplugs (five models) and a small group of test subjects (seven). However the results suggest that the following advice is necessary for those using or intending to purchase custom-moulded earplugs:

- A certain level of skill, training and experience is required to take ear impressions for custom-moulded earplugs. During this study, earplugs moulded by inexperienced users gave low attenuation values. Therefore use skilled, trained and experienced personnel to make ear impressions for custom-moulded earplugs.

- Users should be aware that the actual attenuation afforded by custom-moulded earplugs might be less than the manufacturer's published data. This is generally true of all hearing protectors.

- Comfort is an individual judgement. If comfort is an issue, take up the offers made by some manufacturers/suppliers to have uncomfortable earplugs modified.

1 INTRODUCTION

Mr Tim Ward, HM Principal Specialist Inspector (Noise & Vibration) with the Health & Safety Executive (HSE), requested assistance from the Health & Safety Laboratory's (HSL) Noise and Vibration Team in evaluating the attenuation performance of a sample of CE-marked custom-moulded earplugs in comparison with the attenuation data supplied by the manufacturers of the earplugs.

The Personal Protective Equipment Regulations 2002 (PPE Regulations 2002), the UK transposition of the European Directive on Personal Protective Equipment (PPE) 89/686/EEC, set out requirements which relate to the placing of personal protective equipment products on the market. BS EN 352-2:2002 "Hearing protectors – General requirements – Part 2: Ear-plugs" is a transposed harmonised standard that sets requirements for personal hearing protection, compliance with which provides a means to comply with some of the Essential Requirements of Directive 89/686/EEC.

Five custom-moulded earplug models were selected. Each model was supplied either by the manufacturer directly or by an approved UK agent. Seven subjects were used for the moulding of the earplugs. Three models were moulded on seven subjects and two models were moulded on six subjects. The subjects had varying degrees of experience with custom-moulded earplugs but all were professional noise specialists, so had some understanding of the principles of achieving effective in-ear hearing protection.

Thirty-three sets of custom-moulded earplugs were tested at the acoustic laboratories of the School of Computing, Science and Engineering at the University of Salford, according to the standard BS EN 24869-1:1993. The University facilities are UKAS (United Kingdom Accreditation Service) accredited for this type of testing (see Appendix A for the full UKAS schedule).

There are several factors that may influence the results obtained from tests carried out for HSL by the University of Salford compared with the attenuation data provided by the manufacturer. For example:

- Use of a third party for taking moulding impressions instead of an individual trained by the manufacturer;
- Change in the manufacturing process since certification of the earplug model;
- Change in the material used to make the earplugs.

This report compares the manufacturer's attenuation data with the attenuation data from HSL's testing and seeks to identify factors that may influence any differences observed. All data has been anonymised.

2 CUSTOM-MOULDED EARPLUGS

2.1 MAKING CUSTOM-MOULDED EARPLUGS

Custom-moulded earplugs are made to fit an individual and are not a ‘one size fits all’ solution as is the case with disposable foam earplugs for example.

In order to make a pair of custom-moulded earplugs, precise impressions must be taken of the user’s ears. Every person has a different ear shape and the shape also differs between left and right ears on the same user. An impression is a cast of the ear shape. To make a cast, a small foam stop is first placed into the ear canal next to the eardrum. A fast setting putty-type substance, generally non-allergenic silicon, is then gently squeezed into the full shape of the ear *i.e.* the ear canal, the helix and the concha bowl (see Figure 1). The foam stop prevents the silicon from reaching the eardrum. The casts are left in position for 10-15 minutes to allow them to set. They are then carefully removed from the user’s ear.

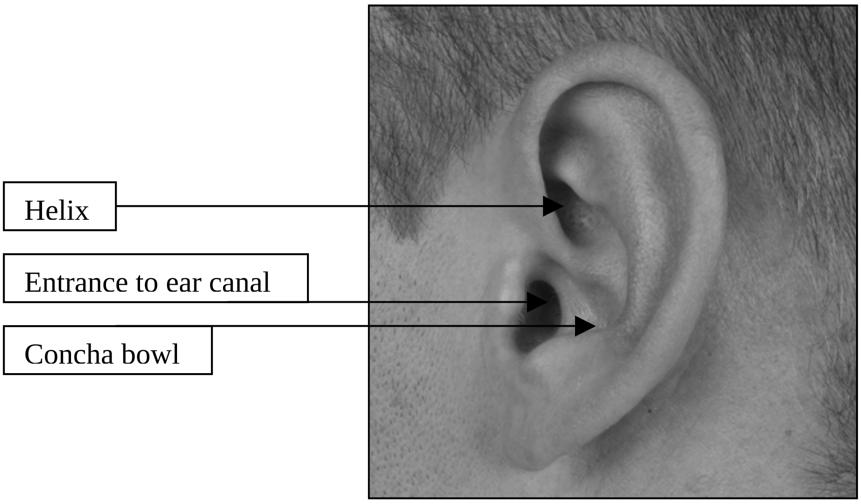


Figure 1. The human outer ear

The impression is trimmed to remove the foam stop and any excess material. This impression is then the basis for making the personalised earplug pair.

2.2 TYPES & FEATURES AVAILABLE

Custom-moulded earplugs are available in different types and with different features. These include, but are not limited to:

- Solid (full concha): Where the earplug fills the ear canal, the concha bowl and the helix. There are no filter devices or holes in the mould;

- Solid (in-canal only): Where the earplug fills the ear canal and the entrance to the ear canal but not the whole concha bowl and not the helix;

- Vented (passive filter): As for solid but with a channel through the earplug, in which a passive acoustic noise filter is placed. Different types of filters can be selected for specific applications;

- Dished: As for solid but where the concha bowl part of the earplug is concave rather than flush with the anatomy of the ear. Often used by motorcyclists for comfort under helmets;

- Metal detectable: Where a small stainless steel ball is bonded into the earplug. Generally used in the food industry;

- Corded: Where a cord connects the earplugs for the left and right ears.

2.3 LIFE SPAN

The lifespan of a custom-moulded earplug can be dependent on a number of factors. These include:

- The material from which the earplugs have been made;

- Frequency of use (wear and tear).

Manufacturer information indicates the life span of custom-moulded earplugs to be between four and seven years. Although not related to the product, the changing shape of a user's ear may also limit the life span of a custom-moulded earplug.

3 SUBJECT SELECTION

Seven subjects were used for the purposes of this research. The subjects had varying degrees of experience with custom-moulded earplugs (from none to very experienced). The variation in experience reflected the variation likely to occur among the population of real end users of the products. No training was given to the subjects prior to earplug moulding or testing. All subjects had an in-depth knowledge of noise issues and noise control solutions. Table 1 details the subjects' experience with custom-moulded earplugs.

Table 1. Subject experience of custom-moulded earplugs

Subject ID	Gender	Age	Experience
Subject 1	Male	49	Some previous experience.
Subject 2	Female	41	No previous experience.
Subject 3	Male	36	No previous experience.
Subject 4	Female	30	Very experienced user. Trained test subject.
Subject 5	Male	41	Some previous experience.
Subject 6	Male	51	Experienced user (motorcycle applications).
Subject 7	Male	40	Some previous experience.

Clause 4.4 of BS EN 24869-1:1993 gives very detailed criteria that the test subjects must meet in order to be considered as 'normal' subjects. These criteria were not always met for the seven subjects used. Again, this reflected the variety of potential end users. Table 2 details subject conformance with the Clause 4.4 criteria.

Table 2. Variation in subject conformation with Clause 4.4 Test subjects

Clause	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	Subject 6	Subject 7
4.4.1*	✓	✓	✓	✓	✓	✓	✗
4.4.2	✓	✓	✓	✓	✓	✓	✓
4.4.3	Not carried out.						

*Subject audiograms are shown in Appendix C

The text from Clause 4.4 is reproduced here for information only:

4.4.1 Subjects to be used in the tests shall have a hearing threshold level by earphone listening in either ear of no more than 15 dB for frequencies of 2 000 Hz and below, and of no more than 25 dB for frequencies above 2 000 Hz. When the background noise in the test room is at the maximum levels listed in Table 2 (see BS EN 24869), subjects with hearing threshold levels lower than – 10 dB shall be rejected.

4.4.2 Subjects shall be selected without regard to sizes and shapes of heads and ears except that those with obvious abnormalities affecting the fitting of hearing protectors shall be excluded.

4.4.3 Subjects used for the test shall have demonstrated the ability to provide three consecutive complete audiograms for the test signals given in 4.1 (see BS EN 24869), with differences between the thresholds of hearing at corresponding centre frequencies not exceeding 6 dB.

NOTE 7 Untrained subjects should first be given practice sessions.

4 PRODUCT SELECTION

4.1 SEARCHING FOR MANUFACTURERS, MODELS AND SUPPLIERS

An initial list of twenty suppliers of custom-moulded earplugs was created using internet searches, journal searches and consultation with noise-specialist colleagues throughout the UK. Some of the suppliers identified were the manufacturers of their own products; others were acting on behalf of European or international manufacturers. Further investigation into the supply chain revealed that some suppliers were offering the same models of earplug from the same manufacturer under the same brand name.

Selection criteria as specified by the HSE customer were applied to the list of twenty suppliers. These criteria were:

- Earplug models had to be CE marked (details about CE marking are given in Appendix B);

- Suppliers or manufacturers taking the ear impressions, from which the plugs were made, had to either be able to travel to the seven subjects, or have agents local to the subjects.

With the application of the selection criteria, the list of 20 potential suppliers/manufacturers was reduced to five.

4.2 THE SELECTED MODELS

Table 3 details the models selected.

Table 3. Details of selected custom-moulded earplugs

Earplug model ID	Type	Supplier or Manufacturer	Source of ear impressions
A	Filtered; in-canal; corded	Supplier	Supplier
B	Vented; full concha	Manufacturer	Agent
C	Vented; full concha; corded	Manufacturer	Manufacturer
D	Solid; full concha	Supplier	Subject
E	Solid; full concha	Manufacturer	Manufacturer

All the selected models carried a CE mark.

Figure 2 is an example of custom-moulded earplug models (neither of the models depicted were used in this study; the figure is for illustration only).

Figure 2. Examples of custom-moulded earplugs

Directive 89/686/EEC requires manufacturers to demonstrate the ability of their hearing protectors to reduce noise. BS EN 352-2:2002 provides the means to comply with the directive and in turn calls on BS EN 24869-1:1993. This standard specifies a subjective method for measuring hearing protector attenuation in which the hearing threshold of sixteen subjects is measured with and without the hearing protector worn. The difference between these two measurements is taken as the noise attenuation.

Tests are carried out in a diffuse sound field using one-third octave bands of pink noise centred on the following centre frequencies: 63 Hz (optional), 125 Hz, 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, and 8000 Hz. The standard procedure requires a minimum of two samples of the hearing protector under test to be used. The samples are distributed evenly among the subjects, and subjects wear the same protector throughout the test. Prior to the tests, subjects are instructed on how to fit the protector properly based on the information provided by the manufacturer with the protector under test. The experimenter may provide additional help as necessary, for example verbal clarification or physical assistance in adjusting the device in conformance with the written instructions.

Hearing protector manufacturers derive the mean value and standard deviation at each test frequency using the noise attenuation data for all sixteen subjects. Assumed protection values (APVs) at each test frequency are determined by subtracting one standard deviation from the mean value. The APV indicates the assumed minimum protection provided to a high percentage of wearers; the use of one standard deviation indicates that the assumed minimum attenuation is likely to be provided to 84% of wearers.

The manufacturer's attenuation values for the models selected for testing are given in Table 4 and Figures 3 and 4 where, as defined in BS EN ISO 4869-2:1995:

- m is the mean sound attenuation determined in accordance with ISO 4869-1
- s is the standard deviation determined in accordance with ISO 4869-1
- α is a constant (for a protection performance of 84% $\alpha = 1.00$)
- APV is the assumed protection value ($m - \alpha s$)
- H is the high-frequency attenuation value

- M is the medium-frequency attenuation value
- L is the low-frequency attenuation value
- SNR is the single-number rating

Table 4. Manufacturer's attenuation data

Model		Attenuation (dB) per frequency band (Hz)								H	M	L	SNR
		63	125	250	500	1000	2000	4000	8000				
A	*m*	-	22.4	23.9	23.7	22.5	22.1	20.4	26.2	18	19	19	20
	s	-	3.3	4.7	3.9	2.4	2.7	4.0	3.9				
	APV	-	19.0	19.2	19.7	20.0	19.4	16.4	22.3				
B	*m*	13.9	16.1	19.0	22.7	25.0	32.2	41.1	36.9	28	21	17	25
	s	6.0	4.2	4.5	4.5	3.4	5.0	4.8	5.0				
	APV	7.9	11.9	14.5	18.2	21.6	27.2	36.3	31.9				
C	*m*	24.3	25.6	25.4	26.7	27.2	35.4	40.8	38.4	31	25	24	29
	s	5.5	4.8	2.5	4.1	2.9	2.6	4.6	5.1				
	APV	18.8	20.8	22.9	22.6	24.3	32.8	36.2	33.3				
D	*m*	21.5	19.3	17.2	16.0	19.7	31.6	35.6	28.8	24	17	15	21
	s	5.1	5.6	3.5	3.2	3.1	4.1	3.5	5.7				
	APV	16.4	13.7	13.7	12.8	16.6	27.5	32.1	23.1				
E	*m*	-	26.7	18.1	22.0	20.9	26.3	32.5	32.8	22.46	18.0	16.51	21.64
	s	-	4.6	4.4	5.0	4.1	4.8	4.5	3.4				
	APV	-	22.1	13.7	17.0	16.8	21.5	28.0	29.4				

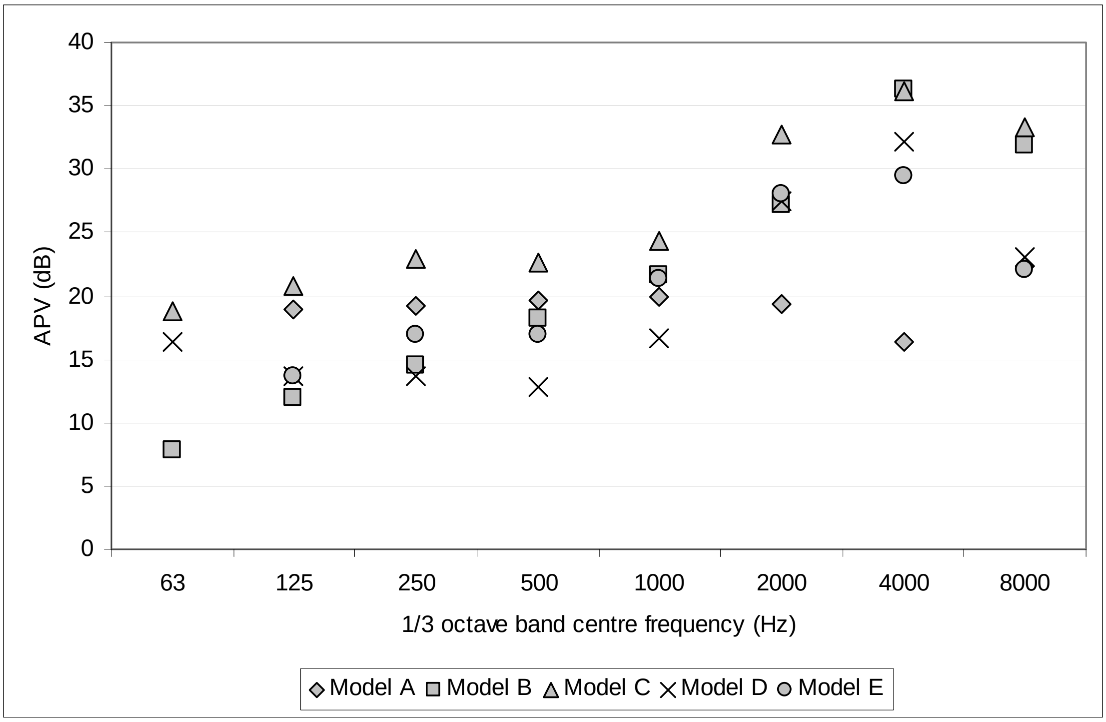


Figure 3. Manufacturer's attenuation values

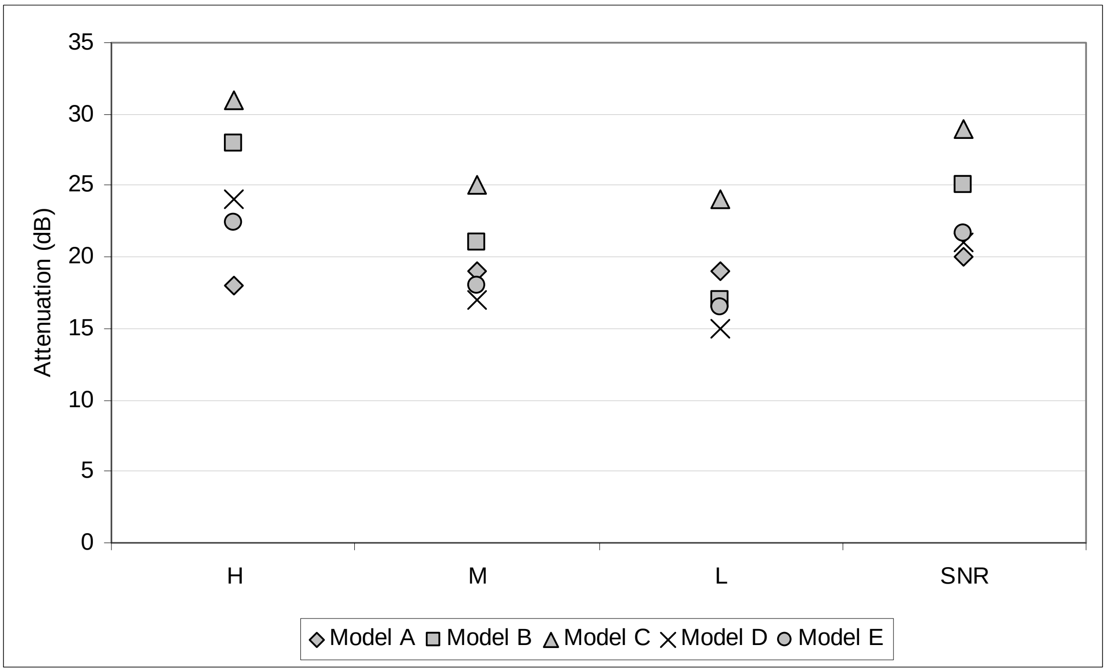


Figure 4. Manufacturer's H, M, L and SNR attenuation values

5 TESTING AND EVALUATION

5.1 TESTING

Seven subjects were used for the moulding and attenuation testing of the custom-moulded earplugs. Three models of earplug were moulded on seven subjects and two models on six subjects. Table 5 details the subject/earplug model matrix.

Table 5. Subject/earplug model matrix

	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	Subject 6	Subject 7
A	✓	✓	✓	✓	✗	✓	✓
B	✓	✓	✓	✓	✓	✗	✓
C	✓	✓	✓	✓	✓	✓	✓
D	✓	✓	✓	✓	✓	✓	✓
E	✓	✓	✓	✓	✓	✓	✓

Subjective testing of the thirty-three sets of custom-moulded earplugs was carried out over three separate days at the acoustic laboratories of the School of Computing, Science and Engineering at the University of Salford in accordance with BS EN 24869-1:1993, where possible. Some deviations from the standard method occurred, for example each protector was only tested on six or seven subjects not the specified sixteen subjects. Other deviations from the standard test are detailed in Table 2.

To overcome the possible effects of subject fatigue, the order in which the earplug attenuation was measured was randomised for each subject. Table 6 details the test order.

Table 6. Measurement order

	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	Subject 6	Subject 7
1st test	A	A	E	D	B	C	C
2nd test	C	B	D	C	✗	E	B
3rd test	E	C	B	A	E	D	D
4th test	D	D	A	B	C	A	E
5th test	B	E	C	E	D	✗	A

5.2 EVALUATION OF ATTENUATION VALUES

The attenuation results provided by the University of Salford for the six or seven subjects were used to calculate a mean attenuation value and population standard deviation for each custom-moulded earplug tested at the specified test frequencies. From these data APV, H, M, L and SNR values were determined for each earplug, using the calculation methods given in BS EN ISO 4869-2:1995. These calculated values are referred to as the HSL attenuation values.

6 RESULTS

The HSL attenuation values are given in Table 7 and Figures 5 and 6. Full attenuation results for all subjects are in Appendix D.

Table 7. HSL attenuation values

Model		Attenuation (dB) per frequency band (Hz)								H	M	L	SNR
		63	125	250	500	1000	2000	4000	8000				
A	m	19.7	19.3	18.3	18.5	19.3	18.8	25.8	20.0	19.1	17.7	17.1	19.5
	s	5.0	7.3	9.3	9.2	5.4	3.4	6.0	5.2	3.1	5.8	7.4	4.7
	APV	14.2	11.4	8.1	8.4	13.4	15.1	19.3	14.3				
B	m	7.0	6.2	7.0	10.2	12.7	24.2	32.0	22.7	20.3	12.7	8.8	16.5
	s	5.1	4.6	4.9	3.6	2.7	4.9	7.7	4.3	2.9	3.0	3.5	3.0
	APV	1.4	1.2	1.7	6.2	9.7	18.8	23.6	18.0				
C	m	12.1	13.4	15.6	18.6	19.4	30.0	33.9	30.0	26.7	19.9	16.8	23.7
	s	3.7	5.1	5.4	6.2	4.9	3.4	5.4	5.5	4.0	4.8	4.8	4.6
	APV	8.1	7.9	9.7	11.9	14.2	26.3	28.0	24.1				
D	m	4.6	4.0	4.9	6.0	7.0	18.7	26.0	16.9	13.5	7.1	5.2	10.8
	s	3.3	4.7	4.6	7.3	7.8	7.2	10.6	6.7	5.6	6.3	4.9	5.6
	APV	1.0	-1.0	-0.2	-1.9	-1.5	10.9	14.6	9.6				
E	m	11.0	12.7	12.0	15.1	15.0	28.1	38.1	30.9	23.5	16.2	13.8	20.3
	s	3.8	6.7	4.4	7.1	6.4	3.9	7.5	7.7	6.0	6.3	5.5	6.1
	APV	6.9	5.5	7.2	7.5	8.0	24.0	30.0	22.5				

It was noted that for all models of earplug, attenuation values for one or two of the subjects were much lower than the rest of the subjects (except Model D where one subject achieved much higher attenuation values). Where this happened, it was not always the same subject.

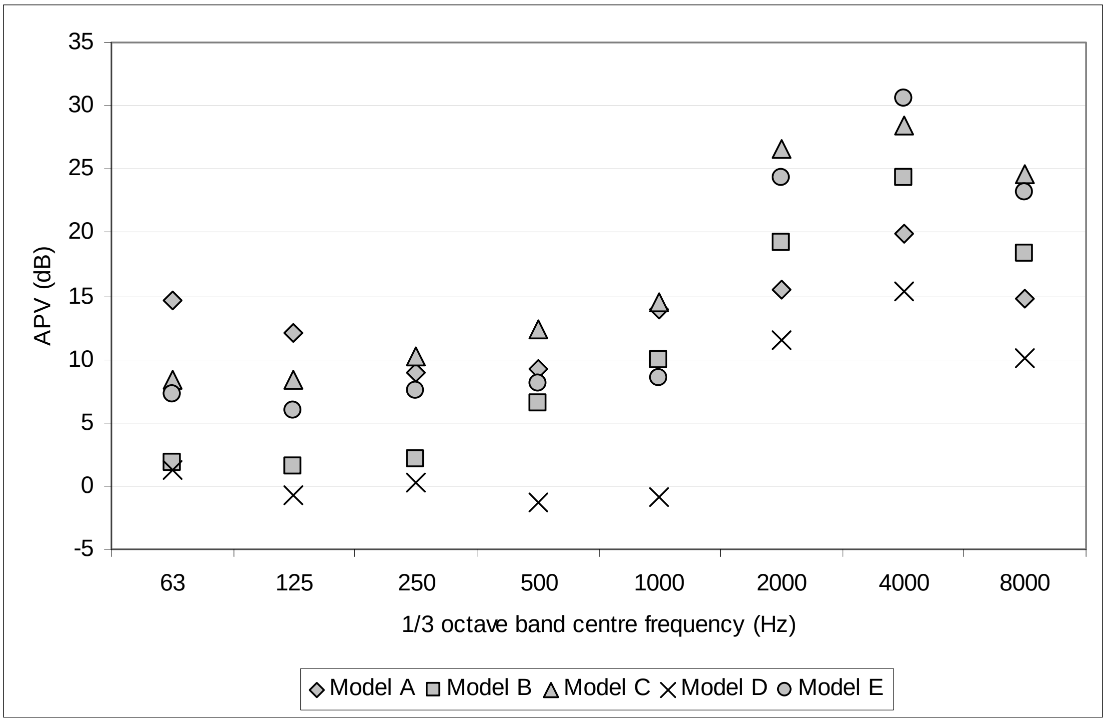


Figure 5. HSL attenuation values

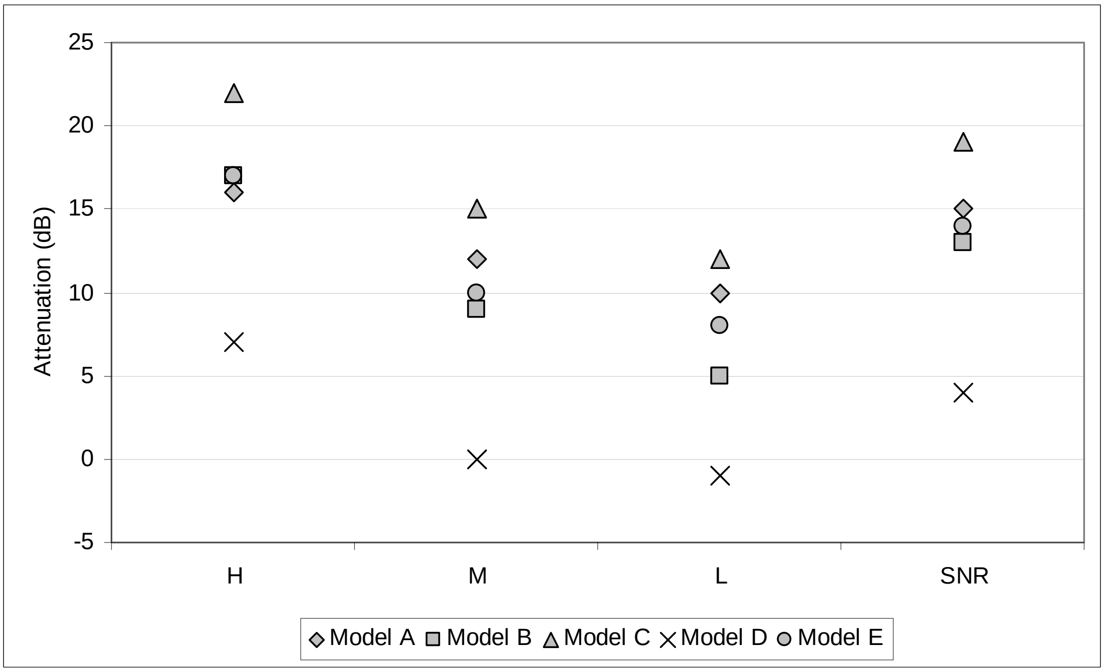


Figure 6. HSL H, M, L and SNR attenuation values

7 COMPARISON AND DISCUSSION

The following nomenclature has been used throughout this section:

- **X Man** custom-moulded earplug model “X”, manufacturer’s attenuation values;
- **X HSL** custom-moulded earplug model “X”, HSL measured attenuation values.

7.1 COMPARISON OF H, M, L AND SNR ATTENUATION VALUES

Table 8 shows the comparison between the attenuation values supplied by the manufacturer, and the mean HSL measured values.

Table 8. Comparison of attenuation values

Model	**Attenuation values (dB)**			
	H	**M**	**L**	**SNR**
A Man	18	19	19	20
A HSL	19.1	17.7	17.1	19.5
Difference	-1.1	1.3	1.9	0.5
B Man	28	21	17	25
B HSL	20.3	12.7	8.8	16.5
Difference	7.7	8.3	8.2	8.5
C Man	31	25	24	29
C HSL	26.7	19.9	16.8	23.7
Difference	4.3	5.1	7.2	5.3
D Man	24	17	15	21
D HSL	13.5	7.1	5.2	10.8
Difference	10.5	9.9	9.8	10.2
E Man	22.46	18	16.51	21.64
E HSL	23.5	16.2	13.8	20.3
Difference	-1.04	1.8	2.71	1.34

7.2 STATISTICAL ANALYSES

The attenuation values presented in Table 8 provide a useful overview of the capability to reduce noise provided by each of the custom-moulded earplugs tested. However the attenuation provided by a particular hearing protector is known to vary between individual wearers due to a number of factors, including physical differences such as head/ear size and the ability to correctly fit the protector. For this reason manufacturers are required to provide data that are based on the distribution of attenuation values obtained during the testing of sixteen subjects using the standard test method specified in BS EN 24869-1:1993.

One of the problems associated with comparing the manufacturers’ attenuation values with the HSL measured attenuation values is that it is possible that an HSL measured attenuation value falling below the mean minus one standard deviation value and/or the mean minus two standard deviations of the manufacturer’s attenuation value could be a valid result. It could represent an attenuation that is drawn from the 16% of the population assumed to receive protection below the mean minus one standard deviation value or from the 5% of the population falling below the mean minus two standard deviations.

A better way of comparing the attenuation values would be to determine whether or not the HSL measured attenuation values were taken from the same distribution as the manufacturers' measured attenuation values. More precisely, there is an assumption that the attenuation values for each subject in the HSL study are taken from a "true distribution" of attenuation values that may or may not be the same as the distribution of the manufacturer's values. The Kolmogorov-Smirnoff test (KS-test) was used to determine this for each model of custom-moulded earplug. It is important to note that the individual attenuation values for the sixteen subjects used to provide the manufacturer's data for each model of earplug were not available. An assumption was therefore made that the manufacturers' attenuation values were normally distributed with the mean and standard deviation data supplied with the earplug.

Table 9 summarises the KS-test results for all custom-moulded earplug models at all test frequencies. 'S' is used to indicate with 99% confidence that the HSL data and the manufacturer's data for each earplug were taken from significantly different distributions. 'NS' is used to indicate with 99% confidence that the distributions from which the HSL data and the manufacturer's data were taken were not significantly different. It is important to note an 'NS' result does not mean that the HSL attenuation values and the manufacturer's attenuation values were taken from the same distribution; it could just be that there was insufficient data to make the statistical test powerful enough to detect a difference.

Of thirty-eight possible test comparisons (i.e. attenuation values for seven or eight frequency bands for five different custom-moulded earplugs), twenty-three of the HSL attenuation values were significantly different from the manufacturers' attenuation values at a 99% confidence level. Full KS-test results and additional plots are given in Appendix E.

Table 9. Summary of KS-test results

Model	Statistical significance per frequency band (Hz)							
	63	125	250	500	1000	2000	4000	8000
A	n/a	NS	NS	NS	NS	NS	NS	NS
B	S	S	S	S	S	S	S	S
C	S	S	S	S	S	S	S	NS
D	S	S	S	S	S	S	NS	S
E	n/a	S	NS	NS	NS	NS	NS	NS

'S' Attenuation values significantly different from manufacturers attenuation values at 99% confidence.
'NS' Attenuation values *not* significantly different from manufacturers values at 99% confidence.

The results in Table 9 show that the attenuation values obtained by HSL for Model A were not significantly different in seven out of seven frequency bands. For Model E, the HSL attenuation values were not significantly different from the manufacturers' attenuation value in six out of seven frequency bands. The manufacturers' and HSL measured attenuation results were shown to be significantly different at all frequencies for Model B, and significantly different in seven out of eight frequency bands for Models C and D. Table 8 shows that all custom-moulded earplugs tested by HSL gave, on average, lower attenuation than the manufacturer's values in terms of the single number attenuation values, i.e. the H, M, L and SNR values.

7.2.1 Model A

Table 10 shows the percentage of HSL measured attenuation values obtained for individual subjects that were at or above the manufacturer's attenuation values for custom-moulded earplug Model A. Ideally, 84% of the HSL measured attenuation values should be at or above the manufacturer's mean attenuation value minus one standard deviation, and 95% should be at or above the manufacturer's mean attenuation value minus two standard deviations. Table 10 also contains the KS-test results for custom-moulded earplug Model A. A comparison of the HSL measured attenuation values for individual subjects compared with the manufacturer's measured attenuation is also shown in Figure 7.

Table 10. Percentage of HSL measured results at or above manufacturer's measured attenuation values and KS-test results for Model A

Model A	Percentage of HSL measured results per frequency band (Hz)							
	63	125	250	500	1000	2000	4000	8000
Man – 1 std dev (84%)	n/a	67	83	67	67	50	83	33
Man – 2 std dev (95%)	n/a	83	83	67	67	67	100	67
Probability (KS-test)	n/a	8.01×10^{-01}	4.46×10^{-01}	4.25×10^{-01}	4.24×10^{-01}	5.33×10^{-02}	1.73×10^{-02}	3.29×10^{-02}
KS-test results	n/a	NS	NS	NS	NS	NS	NS	NS

'S' Difference significant at 99% confidence; 'NS' Difference not significant at 99% confidence

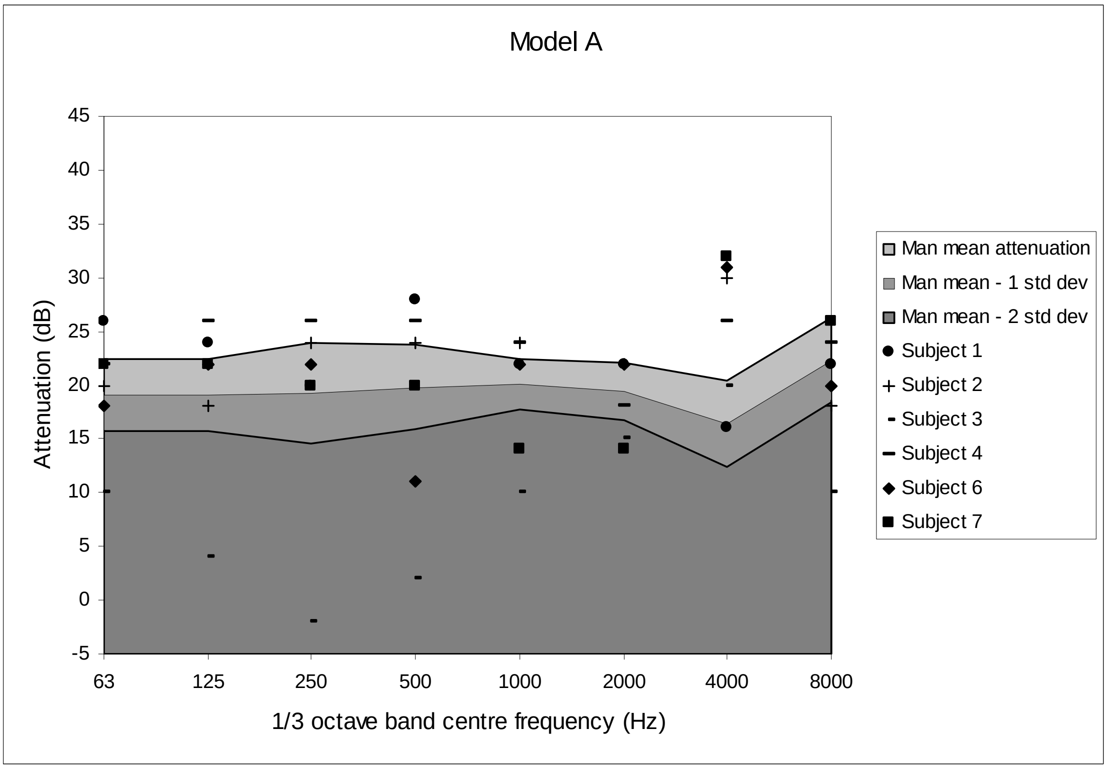


Figure 7. Comparison of HSL measured attenuation values and manufacturer's attenuation values (mean attenuation, mean - 1 std dev, and mean - 2 std dev)

7.2.2 Model B

Table 11 shows the percentage of HSL measured attenuation values obtained for individual subjects that were at or above the manufacturer's attenuation values for custom-moulded earplug Model B. Ideally, 84% of the HSL measured attenuation values should be at or above the manufacturer's mean attenuation value minus one standard deviation, and 95% should be at or above the manufacturer's mean attenuation value minus two standard deviations. Table 11 also contains the KS-test results for custom-moulded earplug Model B. A comparison of the HSL measured attenuation values for individual subjects compared with the manufacturer's measured attenuation is also shown in Figure 8.

Table 11. Percentage of HSL measured results at or above manufacturer's measured attenuation values and KS-test results for Model B

Model B	Percentage of HSL measured results per frequency band (Hz)							
	63	125	250	500	1000	2000	4000	8000
Man – 1 std dev (84%)	17	17	0	0	0	50	17	0
Man – 2 std dev (95%)	100	50	33	33	0	50	50	33
Probability (KS-test)	6.92×10^{-04}	3.96×10^{-05}	1.12×10^{-05}	7.08×10^{-10}	8.88×10^{-15}	3.52×10^{-03}	2.31×10^{-03}	5.60×10^{-09}
KS-test results	S	S	S	S	S	S	S	S

'S' Difference significant at 99% confidence; 'NS' Difference not significant at 99% confidence

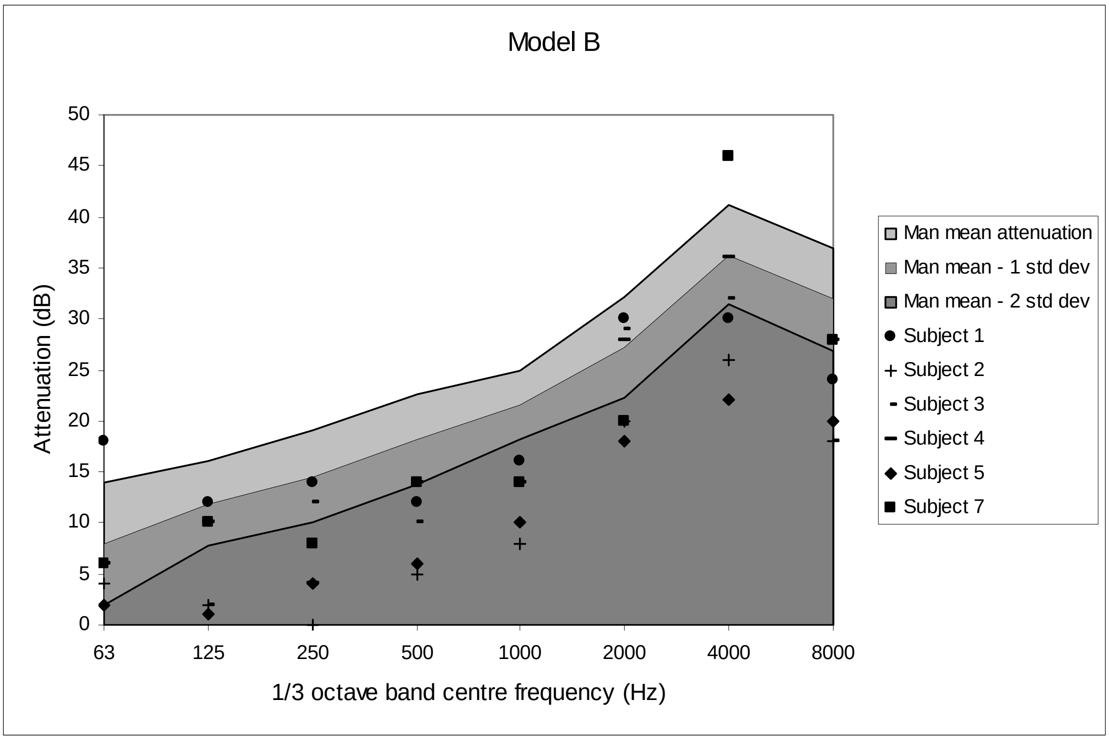


Figure 8. Comparison of HSL measured attenuation values and manufacturer's attenuation values (mean attenuation, mean - 1 std dev, and mean - 2 std dev)

7.2.3 Model C

Table 12 shows the percentage of HSL measured attenuation values obtained for individual subjects that were at or above the manufacturer's attenuation values for custom-moulded earplug Model C. Ideally, 84% of the HSL measured attenuation values should be at or above the manufacturer's mean attenuation value minus one standard deviation, and 95% should be at or above the manufacturer's mean attenuation value minus two standard deviations. Table 12 also contains the KS-test results for custom-moulded earplug Model C. A comparison of the HSL measured attenuation values for individual subjects compared with the manufacturer's measured attenuation is also shown in Figure 9.

Table 12. Percentage of HSL measured results at or above manufacturer's measured attenuation values and KS-test results for Model C

Model C	Percentage of HSL measured results per frequency band (Hz)							
	63	125	250	500	1000	2000	4000	8000
Man – 1 std dev (84%)	0	0	0	43	14	29	29	43
Man – 2 std dev (95%)	57	43	29	57	43	43	57	43
Probability (KS-test)	1.01×10^{-06}	7.89×10^{-07}	7.49×10^{-08}	5.88×10^{-03}	3.16×10^{-04}	5.13×10^{-04}	1.28×10^{-03}	1.60×10^{-02}
KS-test results	S	S	S	S	S	S	S	NS

'S' Difference significant at 99% confidence; 'NS' Difference not significant at 99% confidence

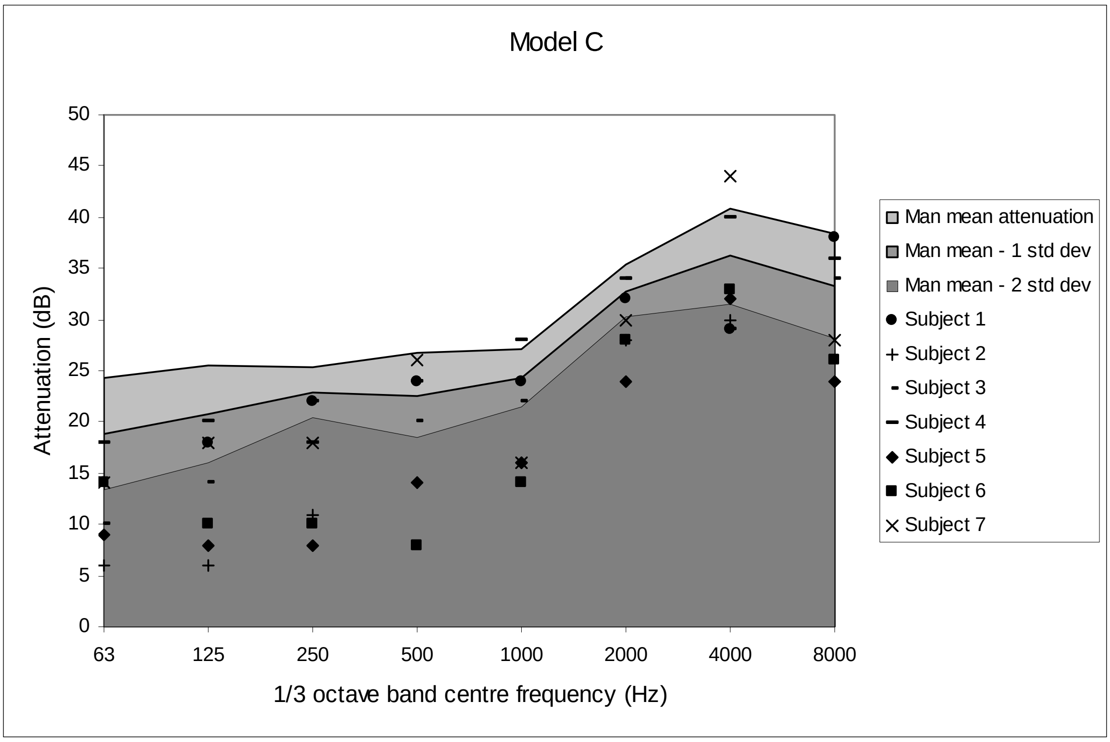


Figure 9. Comparison of HSL measured attenuation values and manufacturer's attenuation values (mean attenuation, mean - 1 std dev, and mean - 2 std dev)

7.2.4 Model D

Table 13 shows the percentage of HSL measured attenuation values obtained for individual subjects that were at or above the manufacturer's attenuation values for custom-moulded earplug Model D. Ideally, 84% of the HSL measured attenuation values should be at or above the manufacturer's mean attenuation value minus one standard deviation, and 95% should be at or above the manufacturer's mean attenuation value minus two standard deviations. Table 13 also contains the KS-test results for custom-moulded earplug Model D. A comparison of the HSL measured attenuation values for individual subjects compared with the manufacturer's measured attenuation is also shown in Figure 10.

Table 13. Percentage of HSL measured results at or above manufacturer's measured attenuation values and KS-test results for Model D

Model D	Percentage of HSL measured results per frequency band (Hz)							
	63	125	250	500	1000	2000	4000	8000
Man – 1 std dev (84%)	0	0	14	29	14	14	43	29
Man – 2 std dev (95%)	0	29	14	29	14	29	43	57
Probability (KS-test)	0.00	1.52×10^{-07}	2.99×10^{-06}	4.06×10^{-04}	3.32×10^{-06}	7.01×10^{-05}	1.44×10^{-02}	7.94×10^{-04}
KS-test results	S	S	S	S	S	S	NS	S

'S' Difference significant at 99% confidence; 'NS' Difference not significant at 99% confidence

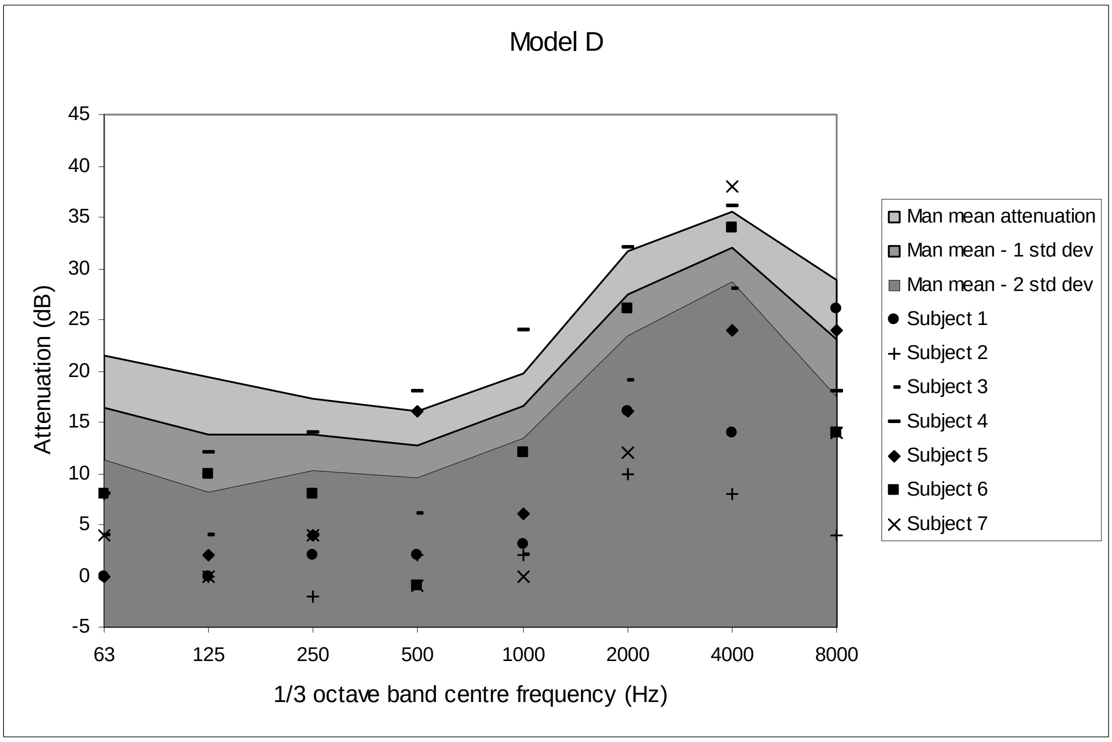


Figure 10. Comparison of HSL measured attenuation values and manufacturer's attenuation values (mean attenuation, mean - 1 std dev, and mean - 2 std dev)

7.2.5 Model E

Table 14 shows the percentage of HSL measured attenuation values obtained for individual subjects that were at or above the manufacturer's attenuation values for custom-moulded earplug Model E. Ideally, 84% of the HSL measured attenuation values should be at or above the manufacturer's mean attenuation value minus one standard deviation, and 95% should be at or above the manufacturer's mean attenuation value minus two standard deviations. Table 14 also contains the KS-test results for custom-moulded earplug Model E. A comparison of the HSL measured attenuation values for individual subjects compared with the manufacturer's measured attenuation is also shown in Figure 11.

Table 14. Percentage of HSL measured results at or above manufacturer's measured attenuation values and KS-test results for Model E

Model E	Percentage of HSL measured results per frequency band (Hz)							
	63	**125**	**250**	**500**	**1000**	**2000**	**4000**	**8000**
Man – 1 std dev (84%)	n/a	14	43	43	57	86	100	57
Man – 2 std dev (95%)	n/a	29	71	86	57	100	100	57
Probability (KS-test)	n/a	8.97 x 10^{-06}	1.93 x 10^{-02}	3.12 x 10^{-02}	1.17 x 10^{-01}	2.78 x 10^{-01}	7.06 x 10^{-02}	1.48 x 10^{-01}
KS-test results	n/a	S	NS	NS	NS	NS	NS	NS

'S' Difference significant at 99% confidence; 'NS' Difference not significant at 99% confidence

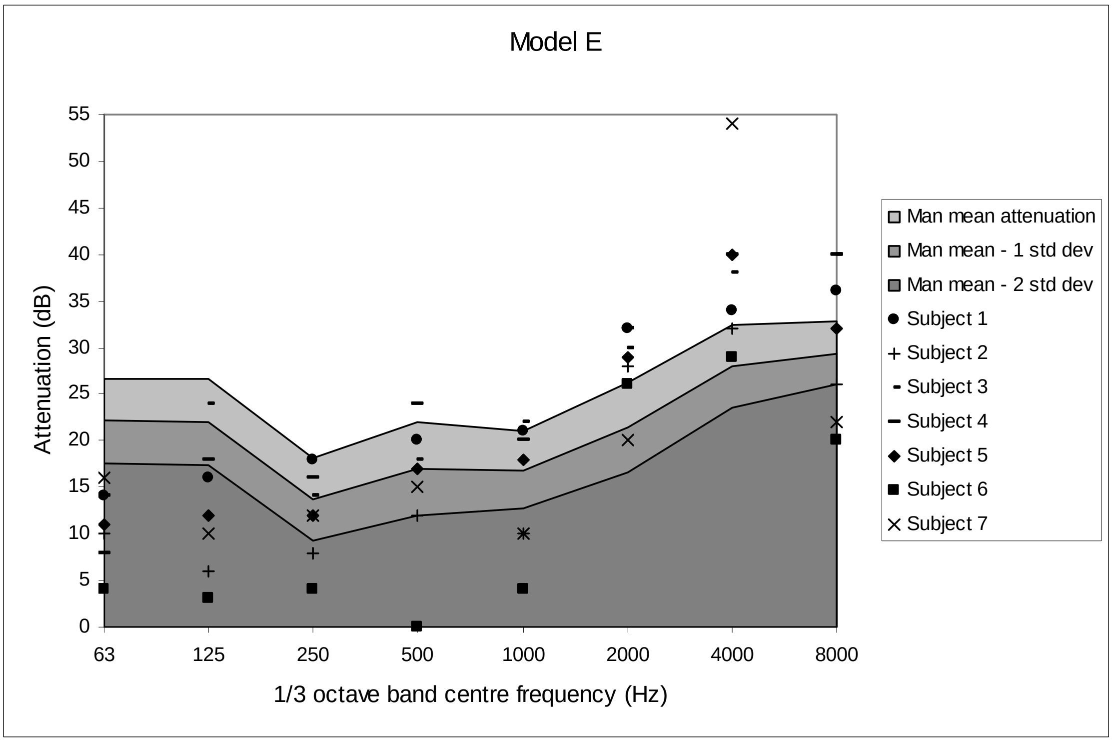


Figure 11. Comparison of HSL measured attenuation values and manufacturer's attenuation values (mean attenuation, mean - 1 std dev, and mean - 2 std dev)

7.3 POSSIBLE INFLUENCES ON THE HSL RESULTS

There are factors other than those already highlighted (e.g. subject experience), which may have influenced the HSL measured attenuation values compared with the manufacturers' attenuation data. These include:

- **Who takes the impressions?**
  Making an impression of the human ear requires skill and training. Whilst the method by which impressions are made shouldn't, in theory, differ from one person to the next, there is always scope for differences in technique.

- **How the impressions are taken**
  The process by which the custom-moulded impressions and earplugs are made may have changed since the model in question was first tested and CE marked. This could entail the use of more accurate trimming tools, better magnification and visibility at a workstation, and improvement in staff training.

- **Availability of new materials**
  Technological and materials science advancements have made new materials available to manufacturers. A series of small changes to a material could change the attenuation properties of the earplug since it was first tested and CE marked.

- **Fit comfort**
  If a subject found the fit of their custom-moulded earplugs uncomfortable during the HSL subjective testing at the University of Salford, this may have lead to distraction, potentially giving false attenuation results. The comfort of a custom-moulded earplug is very personal and can depend, for example, on the model shape or the material hardness.

- **Subject has a pre-existing condition**
  A build up of wax in the ear, or an as yet undiagnosed hearing loss, can both affect the attenuation results. Untreated wax has a tendency to compact if earplugs are repeatedly inserted into and removed from the ear.

  The subjects were not asked about pre-existing hearing conditions. Their audiograms and unoccluded thresholds of hearing were monitored for anomalous results.

7.4 COMPARISON AGAINST BS EN 352-2:2002

BS EN 352-2:2002 sets requirements for personal hearing protection devices in relation to the European Directive on Personal Protective Equipment (PPE) Directive 89/686/EEC. A summary of those BS EN 352-2:2002 requirements applicable to the study reported here is given in Table 15, which also includes an indication of how well the five custom-moulded earplugs tested performed against the specified criteria.

Although not a requirement of the standard, Regulation 12.1 of the PPE Regulations 2002 states:

Subject to the following paragraphs of this regulation, PPE which either meets the basic health and safety requirements or is presumed to do so in accordance with regulation 8(2)(a) shall bear the CE marking in a visible, legible and indelible form.

Also included in Table 15 is an indication of whether the five custom-moulded earplug models meet this criterion.

Table 15. Details of performance against applicable criteria in BS EN 352-2:2002

BS EN 352-2:2002 Applicable clause number & description		Model				
		A	**B**	**C**	**D**	**E**
4.2	**Materials and construction**					
4.2.2.1	No physical damage to wearer	✓	✓	✓	✓	✓
4.2.2.2	Protrusion construction safe	✓	✓	✓	✓	✓
4.2.2.3	Removal without tools	✓	✓	✓	✓	✓
4.2.2.4	Re-closeable hygienic storage	✓	✓	✓	✓	✓
4.3	**Performance**					
4.3.6	Minimum attenuation	✓	✓	✓	✓	✓
5	**Marking**					
5 a	Manufacturer name/trademark/ID	✓	✓	✓	✓	✓
5 b	Model name	×	✓	✓	✓	P
5 c	EN 352	×	✓	✓	✓	✓
5 d	Disposable/re-usable	×	✓	✓	✓	×
5 e	Fitting instructions	✓	×	✓	✓	✓
5 f	Marking for each ear	✓	×	✓	×	P
6	**Information supplied by the manufacturer**					
6.1	Information in English	✓	✓	✓	✓	✓
6.2 a	EN 352-2:2002 mark	×	✓ 1993	✓ 1993	✓	✓
6.2 b	Manufacturer name/trademark/ID	✓	✓	✓	✓	✓
6.2 c	Model name	×	✓	✓	✓	P
6.2 f	Fitting instructions	✓	×	✓	✓	✓
6.2 i 1	Mean & std dev at each test freq	×	✓	✓	✓	✓
6.2 i 2	APV	×	✓	✓	✓	✓
6.2 i 3	HML	×	✓	✓	✓	✓
6.2 i 4	SNR	×	✓	✓	✓	✓
6.2 j 1	Recommendation to use instructions	×	✓	✓	×	×
6.2 j 2	Noisy surroundings	✓	×	✓	×	✓
6.2 j 3	Regularly inspected	P	P	✓	×	✓
6.2 k	Impaired protection warning	×	✓	✓	✓	×
6.2 l	Interconnecting cord warning	×	n/a	✓	n/a	n/a
6.2 n	Cleaning instructions	✓	✓	✓	✓	✓
6.2 o	Chemical substances warning	×	P	✓	✓	✓
6.2 p	Storage before & after use	✓	×	✓	×	✓
6.2 r	Address for additional information	✓	✓	✓	×	✓
PPE Regs 2002, regulation 12.1 CE mark		×	✓	✓	✓	P

Key: ✓ 'Clause fully met'; × 'Clause not met'; **n/a** 'Clause not applicable to this model';
P 'Presentation of information could be improved'

7.5 MINIMUM ATTENUATION ACCORDING TO BS EN 352-2:2002

Clause 4.3.6 of BS EN 352-2:2002 states that earplugs shall have mean minus one standard deviation values of a certain minimum magnitude. Table 16 shows how the HSL measured attenuation for each custom-moulded earplug tested performed against this criterion.

Table 16. Comparison of HSL measured attenuation values with the minimum attenuation requirement

Model		Mean – 1 std.dev. per frequency band (Hz)							
		63	125	250	500	1000	2000	4000	8000
BS EN 352-2:2002 minimum attenuation requirement		-	5	8	10	12	12	12	12
A	HSL measured	14.7	12.1	9.0	9.3	14.0	15.4	19.9	14.8
	Satisfied?	-	✓	✓	✗	✓	✓	✓	✓
B	HSL measured	1.9	1.6	2.1	6.6	9.9	19.3	24.3	18.4
	Satisfied?	-	✗	✗	✗	✗	✓	✓	✓
C	HSL measured	8.4	8.3	10.2	12.4	14.6	26.6	28.4	24.5
	Satisfied?	-	✓	✓	✓	✓	✓	✓	✓
D	HSL measured	1.2	-0.7	0.2	-1.3	-0.8	11.5	15.4	10.1
	Satisfied?	-	✗	✗	✗	✗	✗	✓	✗
E	HSL measured	7.2	6.0	7.6	8.0	8.6	24.3	30.6	23.2
	Satisfied?	-	✓	✗	✗	✗	✓	✓	✓

7.6 MODEL D – VARIATIONS ON A THEME

Model D differed from all the other custom-moulded earplugs tested during the project in three distinct ways:

- Use of trained personnel producing the plugs was not required, the plugs were designed to be moulded by the subjects themselves;

- No separate impression was made; the impression was the final product;

- The small foam stop inserted into the ear canal prior to moulding for other plugs was not required.

Figure 12 shows six of the seven sets of earplugs for Model D.

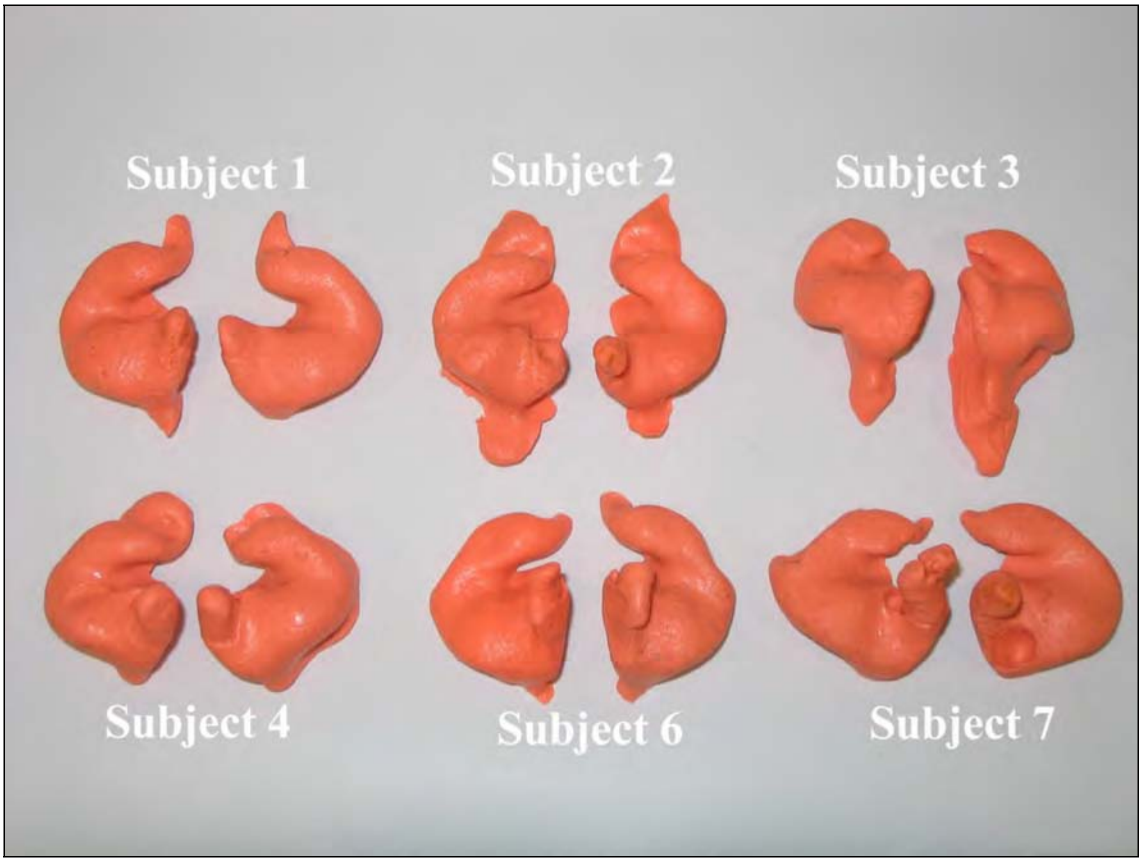


Figure 12. Model D

From Figure 12 it can be seen that every sample of custom-moulded earplug Model D is different, between the left and right ear of the same subject, and also between subjects. The impressions for Subject 4 most closely resemble impressions made by trained individuals. Subject 4 achieves the highest attenuation values (this is clearly shown in Figure 10), and is also the most experienced custom-moulded earplug subject.

For Model D the impression was also the final product, therefore there was no distinction between when the impression was taken and manufacture of the final product. However it is possible that the number of days between the subjects moulding their own earplug and HSL attenuation testing could be an influencing factor. Table 17 shows the number of days between the moulding and attenuation testing of Model D for each subject.

Table 17. Number of days between moulding and testing of Model D

Model	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5	Subject 6	Subject 7
D	1	0	1	0	1	21	106

Subjects 2 and 4 both made their earplugs on the day of testing. Both subjects removed the plugs and refitted them for testing. The HSL attenuation values for Model D do not appear to be influenced by the number of days between moulding and testing. There was also no visible difference e.g. deterioration of the material, due to the time between manufacture and testing.

7.7 COMFORT INDEX & HEARING PROTECTION

Annex II, Clause 3.5 of the European Directive on Personal Protective Equipment (PPE) 89/686/EEC and Clause 3.5 of the PPE Regulations 2002 state:

3.5. Protection against the harmful effects of noise

… All PPE must bear labelling indicating the noise attenuation level and the value of the comfort index provided by the PPE; should this not be possible, the labelling must be fixed to the packaging.

Annex ZA of BS EN 352-2:2002 details the clauses of the standard addressing the essential requirements or other provisions of EU Directives, in this case the European Directive on Personal Protective Equipment (PPE) 89/686/EEC. It also says:

"Compliance with this Standard provides one means of conforming with the specific essential requirements of the Directives concerned and associated European Free Trade Association (EFTA) Regulations."

Annex ZA indicates that Clause 4.3.6 of BS EN 352-2:2002 satisfies the essential requirement of Clause 3.5 of the Directive. However, in Clause 4.3.6 of the standard there is no reference to comfort index values, only a minimum attenuation requirement. There is no test for the assessment of comfort included in BS EN 352-2:2002, yet there is a "presumption of conformity" with the PPE Regulations 2002, and therefore EU Directive, if hearing protection is tested and CE marked against the standard.

With no standardised test to use, subjects were asked to rate the comfort of the custom-moulded earplugs on a simple five-point scale where:

1 = Very comfortable
2 = Comfortable
3 = Neither comfortable nor uncomfortable
4 = Uncomfortable, would tolerate wearing
5 = Uncomfortable, would not wish to wear

The comfort rating results, for each earplug model, are shown in Table 18.

Table 18. Subjective comfort ratings

	Model				
	A	**B**	**C**	**D**	**E**
Subject 1	2	2	1	5	2
Subject 2	1	3	2	5	2
Subject 3	5	5	4	4	4
Subject 4	5	4	1	5	3
Subject 5	Not applicable	2	3	Unavailable	3
Subject 6	2	Not applicable	2	5	Unavailable
Subject 7	4	1	1	3	3
Average	3.2	2.8	2.0	4.5	2.8

The average score for the subjective comfort rating indicates that Model C was considered by subjects to be the most comfortable. Model D was considered to be the most uncomfortable.

At least one of the custom-moulded earplug suppliers commented, that in the event of discomfort, they would be happy to revisit and modify the earplug where necessary. None of the subjects went back to the suppliers to have uncomfortable earplugs modified.

7.8 ATTENUATION CHARACTERISTICS

Inserting an earplug into the ear removes the ear’s natural resonant peak, which can cause speech to sound muffled. The attenuation characteristics of conventional earplugs can also have a detrimental effect on speech communication because they typically provide more attenuation at higher frequencies than at mid and lower frequencies. Some manufacturers have incorporated filters into the design of their earplugs, which results in attenuation characteristics that follow the natural response of the open ear, i.e. they have a flat response. Other earplugs are vented (i.e. there is a hole through the length of the earplug) and are designed to provide significant high frequency attenuation, but allow lower frequencies to pass through unattenuated.

The HSL measured data for custom-moulded earplug Model A showed relatively flat attenuation characteristics consistent with a filtered earplug. The attenuation characteristics of the HSL data were relatively similar to those provided by the manufacturer.

Although Model B is supplied as a vented earplug, the attenuation characteristics based on the HSL measured data and the manufacturer’s data were more similar to a conventional hearing protector with a gradual increase in the levels of protection with increasing frequency.

The attenuation characteristics of Models C and D based on the HSL data and the manufacturers’ data were comparable, despite Model C being vented and Model D being solid. These earplugs provided relatively flat frequency characteristics (and in the case of Model D almost negligible attenuation) at frequencies up to and including 1 kHz. Above this frequency there was a sharp rise in the levels of protection afforded by these earplugs. The attenuation characteristics of both of these earplugs, based on the HSL measured data, was consistent with a vented earplug. For Model D this may be due to leakage, particularly at low frequency, due to inadequate fit.

The HSL measured data for Model E showed attenuation characteristics consistent with a vented earplug, i.e. negligible attenuation up to and including 1 kHz and then an increase in the level of protection at higher frequencies. The attenuation characteristics based on the HSL data were different to those suggested by the manufacturer’s data, which shows higher levels of protection at low and high frequencies and reduced protection between 250 Hz and 1 kHz.

Following testing, it was noted that for Model A the channel in the right earplug for subject four had not been completely bored.

7.9 SUBJECT AND TEST ENGINEER COMMENTS

Table 19 details comments from the subjects on each of the custom-moulded earplug models. The comments were made before, during and after testing. Subjects were encouraged to use the earplugs during their normal work, where appropriate.

Table 19. Subject comments

	Model A	Model B	Model C	Model D	Model E
Subject 1					
Subject 2	Secure fit.	Fit not secure.			
Subject 3	Cord from left earplug had detached before testing. Louder in the right ear when plug fitted. Fit not secure. Self-generated noise from rubbing of earplug cord. Good storage bag.	Felt comfortable. Appeared to fit well. Performance did not noticeably change when moving head and jaw.	Felt comfortable. Appeared to fit well. Performance did not noticeably change when moving head and jaw.	Plugs felt loose.	Louder in right ear when plug fitted. Fit not secure. Performance changed noticeably when moving head and jaw.
Subject 4		Right earplug did not feel secure.			Earplugs did not feel secure.
Subject 5	Self-generated noise from rubbing of earplug cord.				
Subject 6				A number of attempts required to achieve a subjective satisfactory. Slimy feel.	
Subject 7	Subject removed the cord from earplugs before testing. Soft, but a bit plastic-y. Tricky to fit - sustained force required to get it round the bend in the ear canal. Feels like it's trying to push itself out. Very difficult to fit on left. Feels too big. Application of supplied cream helps it to get in & round the bend.	Soft & flexible. Reasonably easy to fit.	Soft & flexible. Nice fit. Softness makes fitting a little tricky at first.	Very flexible and soft. Not convinced that they are elastic under more than a moderate application of force - or at least slow to reform to original shape. Easy to fit (although I'm worried that the part to be inserted in to ear canal will break off), apart from little bits sticking out at upper helix. Painful on left when applying slight pressure to check fit. Ache develops on left after a few minutes.	Not as soft as C, still flexible. Difficult to fit particularly in right ear (helix); improves with practice. Uncomfortable in left ear canal.

The test engineer made further observations during testing:

- The subjects did not reference manufacturers' instructions during the testing;
- The ear cream that accompanied Model A to assist with fitting was voluntarily used by Subject 7 on the left ear-plug and by Subject 4 on the right ear-plug;
- Subject 6 licked the earplugs before inserting at the time of testing;
- Subject 5 required physical assistance from the test engineer to fit Model E;
- The engineer commented that Subject 7's unoccluded threshold of hearing was changing during testing. After testing an observation using an otoscope revealed a build up of wax in both ears, which was likely to be compacting during the various fittings of earplugs.

7.10 FINAL SUMMARY TABLE

A summary of all the information obtained for each custom-moulded earplug tested is given in Table 20.

Table 20. Summary of results for custom-moulded earplugs

Model	HSL measured attenuation meets minimum attenuation requirements (if not how many frequency bands fail)	Meets other BS EN 352-2:2002 requirements	HSL and manufacturer's attenuation values NOT significantly different	SNR (dB) HSL mean & range / Man	SNR Difference (dB)	Comfort rating 1 = comfortable 5 = uncomfortable; would not wear	Attenuation characteristics (based on HSL data)
A	No; fails in 1 out of 7 bands	No; significant omissions including attenuation data, identifying earplugs as re-usable, and advice to fit, adjust and maintain according to manufacturer's instructions	Yes	HSL 19.5 (9.7 to 23.9) Man 20	-0.5	3.2	Filtered (flat response)
B	No; fails in 4 out of 7 bands	No; some omissions, including fitting instructions and identifying left/right earplugs	No	HSL 16.5 (11.6 to 20.2) Man 25	-8.5	2.8	Resembles conventional
C	Yes	Yes	Partial (1 out of 8 frequency bands)	HSL 23.7 (17.1 to 30.2) Man 29	-5.3	2.0	Vented
D	No; fails in 6 out of 7 bands	No; some omissions, including identifying left/right earplugs, advice to fit, adjust and maintain according to manufacturer's instructions and to regularly inspect	Partial (1 out of 8 frequency bands)	HSL 10.8 (5.9 to 23.4) Man 21	-10.2	4.5	Resembles vented
E	No; fails in 3 out of 7 bands	No; some omissions, including identifying earplugs as re-usable and advice to fit, adjust and maintain according to manufacturer's instructions	Partial (6 out of 7 frequency bands)	HSL 20.3 (8.7 to 26.2) Man 21.64	-1.34	2.8	Resembles vented

8 CONCLUSIONS

For all the custom-moulded earplugs tested, the average measured attenuation values were less than the manufacturer's values in all frequency bands, with the exception of two earplugs: one where measured values were slightly higher in the 2 kHz and 4 kHz frequency bands and one where the measured values were slightly higher in the 4 kHz band only. Consequently, the mean single number attenuation values (H, M, L and SNR) based on the measured attenuation values were lower than the manufacturer's values.

The mean SNR values calculated from the measured attenuation values were between 0.5 dB and 10.2 dB lower than the values provided by the manufacturers, indicating that the in-use noise level perceived by the wearer of the earplugs would be a factor of between 1 and 10 times higher than would be assumed. However, apart from Model D, the mean SNR values for the earplugs, based on the measured attenuation, were between 16.5 dB and 23.7 dB indicating that they provided some protection to the wearer. Model D had a mean SNR value of 10.8 dB, compared with the manufacturer's stated SNR value of 21 dB.

The measured attenuation values for only one earplug (Model C) satisfied the minimum attenuation requirement of BS EN 352-2:2002 in all frequency bands. The measured attenuation values for one earplug (Model D) were less than the minimum attenuation requirement in six out of seven frequency bands, and gave negligible attenuation below 2 kHz.

Statistical analysis estimated that two of the five earplugs (Models A and E) gave measured attenuation values that were in general not significantly different from the manufacturer's values. However the remaining earplugs (i.e. Models B, C and D) had measured attenuation values that were significantly different across all, or all but one, of the frequency bands. This indicates that for these three models, the earplugs being supplied are not represented by the attenuation data supplied with them.

The very poor performance of earplug Model D, designed to be moulded by the user, indicates that the making of a custom-moulded earplug based on precise impressions of the user's ears should not be left to untrained individuals; it requires skill and training.

Earplug users can help to maintain the attenuation performance and the life span of custom-moulded earplugs by using the information and instructions provided by the manufacturer on correct fitting, maintenance (e.g. cleaning and regular inspection) and storage. Although BS EN 352-2:2002 sets requirements for this information to be supplied with the earplugs, only one earplug (Model C) met all of the requirements. A variety of information was missing for all the other earplugs tested including attenuation data, fitting instructions, advice to fit, adjust and maintain in accordance with manufacturer's instructions, advice to regularly inspect, and recommended storage conditions. The absence of some of this information could have a detrimental effect on the performance and life span of the earplug.

Another issue likely to affect the performance of custom-moulded earplugs is the physical characteristics of the user's ears. Whilst an employer is responsible for providing suitable hearing protection, it is the responsibility of the user to inform the employer if the chosen form of hearing protection is unsuitable or uncomfortable in any way. The user should also ensure that their ears are free from obstructions, for example wax. The supplier of the hearing protection also has a role in advising its customer on the suitability of the product.

There is no requirement according to BS EN 352-2:2002 for the comfort of earplugs to be assessed although it is a requirement of Directive 89/686/EEC. Based on a simple five-point scale, the average score for the subjective comfort rating indicated that Model C was considered by the subjects to be the most comfortable. Model D was considered the most uncomfortable. There appeared to be no correlation between comfort and attenuation; the SNR based on the measured attenuation values was highest for Model C (16.8 dB) and lowest for Model D (10.2 dB). Subject comments suggest that comfort could be rated according to the characteristics of the material from which the earplug is made, and a good fit. However there are too few subject comments to say for certain whether or not these factors are important in relation to the comfort of custom-moulded earplugs.

The measured attenuation values showed that Model A had relatively flat attenuation characteristics consistent with the manufacturer's data for a filtered earplug. Although the other models were either vented or solid custom-moulded earplugs, the attenuation characteristics based on the measured data were comparable, i.e. relatively low or negligible attenuation up to and including 1 kHz and then higher attenuation at higher frequencies. This response is generally typical of a vented earplug. The measured attenuation characteristics for all the earplugs, except Model E, were comparable with the manufacturer's data except for lower levels of attenuation across all frequency bands.

Manufacturers of custom-moulded earplugs often claim that users can achieve a superior repeatable fit compared with other forms of hearing protection, giving the user the level of protection claimed by the manufacturer. The data from this study supplied no evidence to support such claims. However, the study did show that by using custom-moulded earplugs, the user is likely to be no worse or no better protected than if they used other forms of hearing protection. The perceived wisdom, that the attenuation afforded by a hearing protector is a few decibels less than the protection claimed by the manufacturer, holds true.

The attenuation characteristics expected of the different types of custom-moulded earplug appear to be verified for filtered and vented earplugs. Claimed flat attenuation was verified in one custom-moulded earplug.

9 RECOMMENDATIONS

It is important to note that the recommendations given here are based on both a small sample of custom-moulded earplugs (five models) and a small group of test subjects (seven). However the results suggest that the following advice is necessary for those using or intending to purchase custom-moulded earplugs:

- A certain level of skill, training and experience is required to take ear impressions for custom-moulded earplugs. During this study, earplugs moulded by inexperienced users gave low attenuation values. Therefore use skilled, trained and experienced personnel to make ear impressions for custom-moulded earplugs.

- Users should be aware that the actual attenuation afforded by custom-moulded earplugs may be less than the manufacturer's published data. This is generally true of all hearing protectors.

- Comfort is an individual judgement. If comfort is an issue, take up the offers made by some manufacturers/suppliers to have uncomfortable earplugs modified.

10 REFERENCES

[1] *BSi The CE Marking Process,* http://www.bsi-global.com/en/ProductServices/About-CE-Marking/The-CE-marking-Process/, accessed on 26 March 2009

[2] BS EN 352-2:2002 *Hearing protectors – General requirements – Part 2: Ear-plugs*

[3] BS EN ISO 4869-2:1995 *Acoustics – Hearing protectors – Part 2: Estimation of effective A-weighted sound pressure levels when hearing protectors are worn*

[4] BS EN 24869-1:1993 (ISO 4869-1:1990) *Sound attenuation of hearing protectors – Part 1: Subjective method of measurement*

[5] *Controlling Noise at Work. The Control of Noise at Work Regulations 2005. Guidance on Regulations* L108 (Second edition) HSE Books 2005 ISBN 0 7176 6164 4

[6] *Directive 89/686/EEC of the European Parliament and of the Council of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment,* Official Journal L 399 , 30/12/1989 P. 0018 - 0038

[7] Hemstock T I and Hill E (1990). *The 'real world' attenuation of hearing protectors,* HSE Contract Research Report: CRR24/1990

[8] Patel J (2008). *Musicians' hearing protection; a review,* HSE Research Report: RR664

[9] *The Personal Protective Equipment Regulations 2002* SI 2002/1144, http://www.opsi.gov.uk/si/si2002/20021144.htm, accessed on 26 March 2009

APPENDIX A – UNIVERSITY OF SALFORD UKAS TEST SCHEDULE

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

21 - 47 High Street, Feltham, Middlesex, TW13 4UN, UK

1262 Accredited to ISO/IEC 17025:2005	**University of Salford** **Issue No:**014 **Issue date:** 03 September 2007	
	School of Computing, Science and Engineering **Newton Building** **The Crescent** **Salford** **Manchester** **M5 4WT**	**Contact: Mr D McCaul** **Tel: +44 (0)161-295 4615** **Fax: +44 (0)161-295 5427** **E-Mail: d.mccaul@salford.ac.uk** **Website:**
Testing performed at the above address only		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HEARING PROTECTORS	Acoustical Testing	
Ear-muffs, helmet mounted ear-muffs and ear plugs	Sound attenuation using the subjective method of measurement	BS EN 24869-1:1993
BUILDING ELEMENTS		
Separating elements including partitions, doors, walls, windows and façade elements	Airborne sound insulation of building elements	BS EN ISO 140-3:1995 BS EN ISO 717-1:1997
BUILDING FINISHES		
Including ceiling panels, wall panels, carpets, curtains, proprietary or purpose made sound absorbent materials, and other room contents including seating, screens and space absorbers	Measurement of sound absorption in a reverberation room	BS EN ISO 354: 2003 BS EN 11654:1997
Floor finishes	Laboratory measurement of the reduction of transmitted impact noise by floor coverings (The properties measured are the differences in Impact Sound Pressure Level with and without floor covering)	BS EN ISO 140-8:1998 BS EN ISO 717-2:1997

Assessment Manager: IKC (1262Testing Single_014) Page 1 of 2

1262 Accredited to ISO/IEC 17025:2005	**Schedule of Accreditation** **issued by** **United Kingdom Accreditation Service** 21 - 47 High Street, Feltham, Middlesex, TW13 4UN, UK **University of Salford** **Issue No:** 014 **Issue date:** 03 September 2007

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
ROAD TRAFFIC NOISE BARRIERS	Laboratory measurement of the acoustical performance of barriers, both sound absorption and sound insulation. (The properties measured are the sound absorption coefficients and the Sound reduction Index, with single figure ratings derived from a specified traffic noise spectrum)	BS EN 1793-1:1998 BS EN 1793-2: 1998 BS EN 1793–3:1998
END		

Assessment Manager: IKC (1262Testing Single_014) Page 2 of 2

APPENDIX B – CE MARKING

From the BSi (British Standards Institute) website:
http://www.bsi-global.com/en/ProductServices/About-CE-Marking/The-CE-marking-Process/

About CE Marking

If you manufacture or import a product, which falls within the scope of one or more of the New Approach Directives and wish to place your product on the market in any of the member states of the European Economic Area (EEA), then you must apply CE marking to your product against the essential requirements of all these applicable directives.

The New Approach Directives will provide a range of compliance routes for your product and show you, usually in a modular format, the available routes to compliance.

You must then decide which is the best fit for your company set up and follow the routes detailed in the Directive.

In many cases the compliance route will require you to use a Notified Body to assist with your certification.

The essential requirements of the New Approach Directives differ from directive to directive and product to product.

The CE Marking Process

Step 1: Identify the Directive(s) that are applicable to your product. You can download these directives free of charge from the European Union website

Step 2: Identify the conformity assessment procedure that must be taken. This could be self-declaration, involve testing, inspection or quality system assessment from a Notified Body or a combination of these. The conformity assessment procedure will differ depending on your product and the Directive in respect of which you will be CE marking.

Step 3: Determine the dates by which you must take action. This will be the date that the Directive comes into force. The majority of directives are already in force. In these cases, it is an offence to place a product on the market without CE marking because it indicates a presumption of conformity with all relevant Legislation.

Step 4: Identify if there are any Harmonised European Standards applicable to your product. These are not always mandatory for manufacturers although there is a presumption that conformity to these standards will give conformity with the relevant part of the Directive. Whenever possible or appropriate, manufacturers should follow harmonised standards.

Step 5: Ensure the product complies with all the essential requirements of the Directive(s). Take appropriate measures to comply or identify existing data and test reports.

Step 6: Identify whether independent assessment of your conformity to the Directive, or some aspects of it, is required from a Notified Body. This will be stated in the directive and is dependent upon the product you are CE marking. You must not affix CE marking to your product until all necessary certifications have been obtained from the Notified Body.

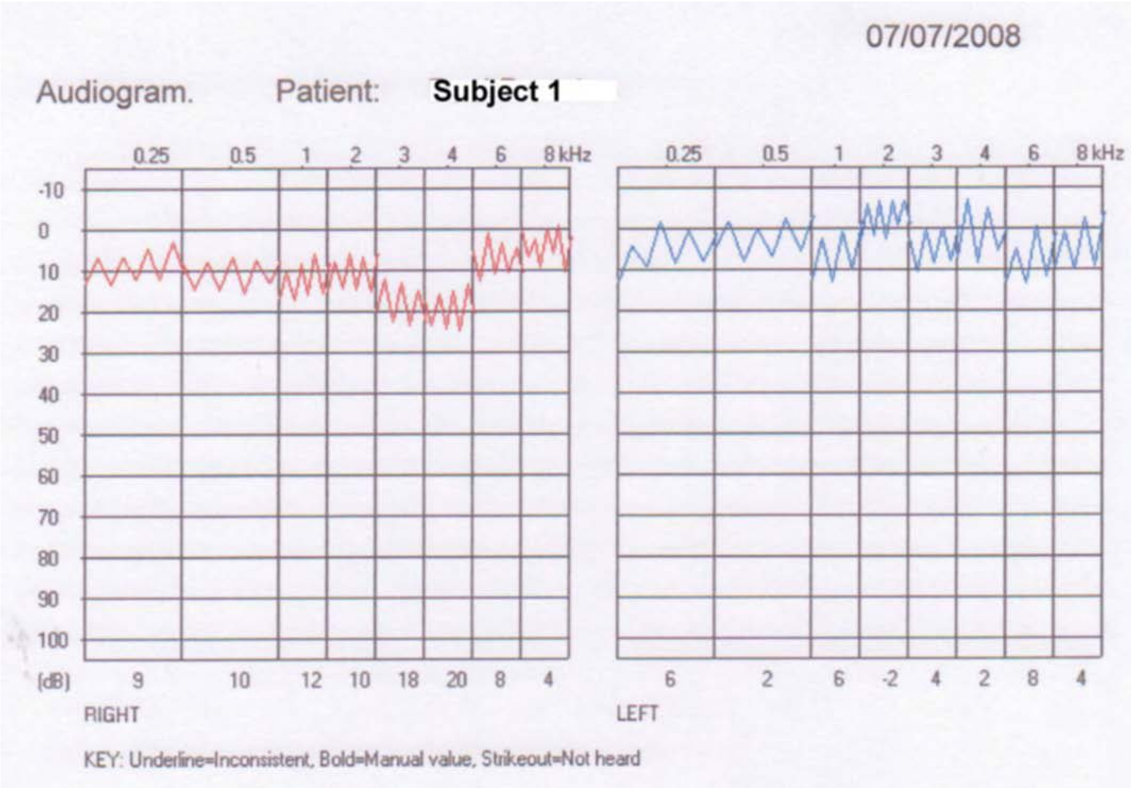
Step 7: Maintain Technical Documentation required by the Directive(s). Your technical documentation should support your compliance with the requirements of the Directive. It is essential to retain this documentation.

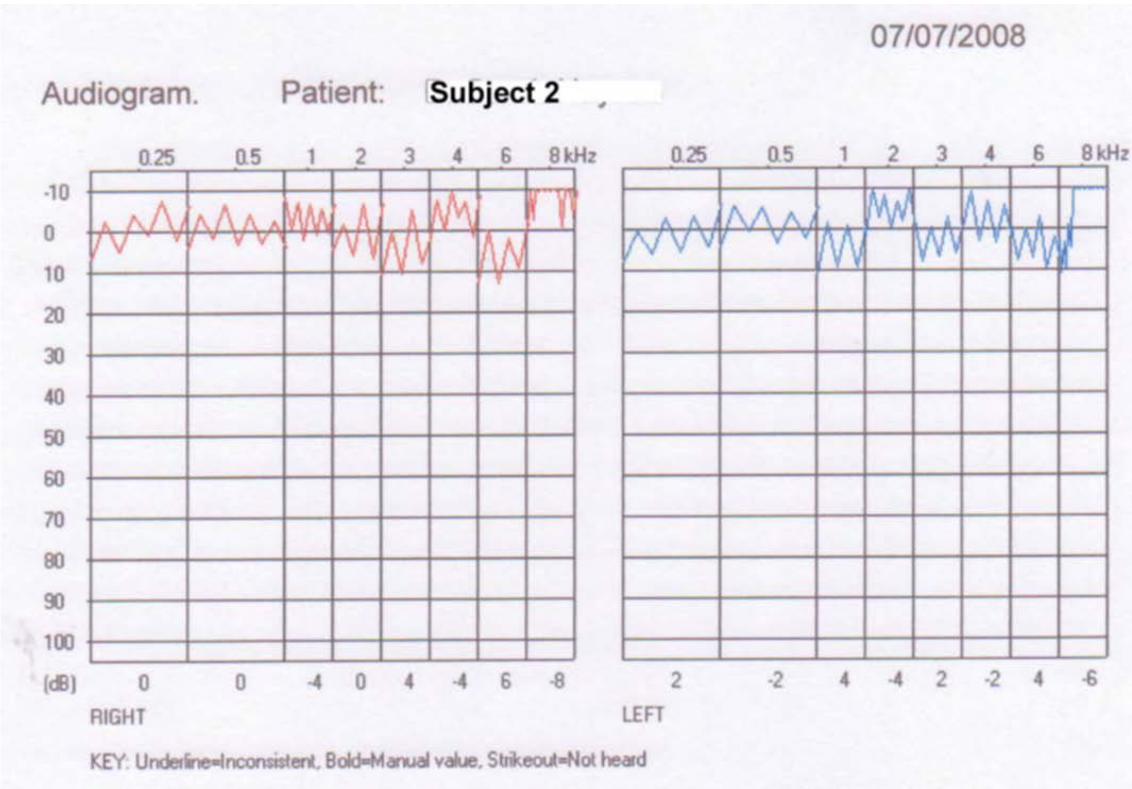
Step 8: Prepare the Declaration of Conformity and the required supporting evidence. The Declaration of Conformity along with the Technical Documentation should be available to Competent Authorities (EU Members) upon request.

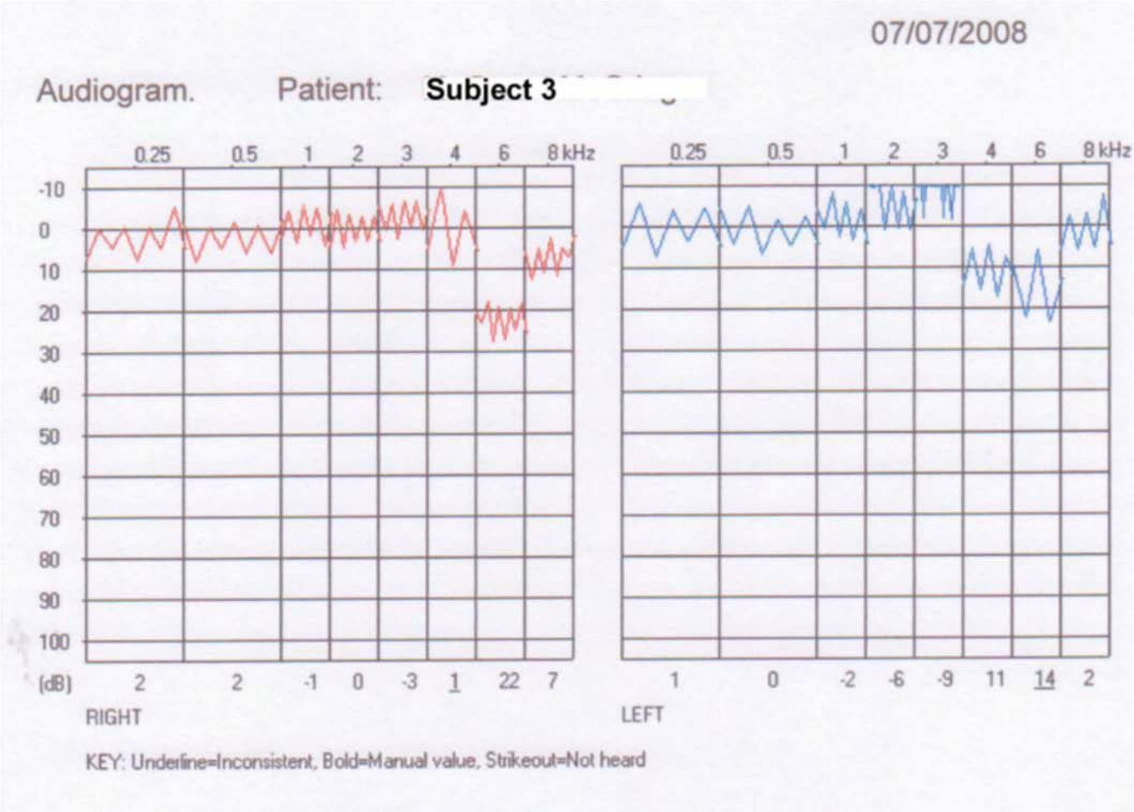
Step 9: Check that no other purely national requirements exist in the countries where the product will be sold. These may include national standards, labelling or packaging requirements.

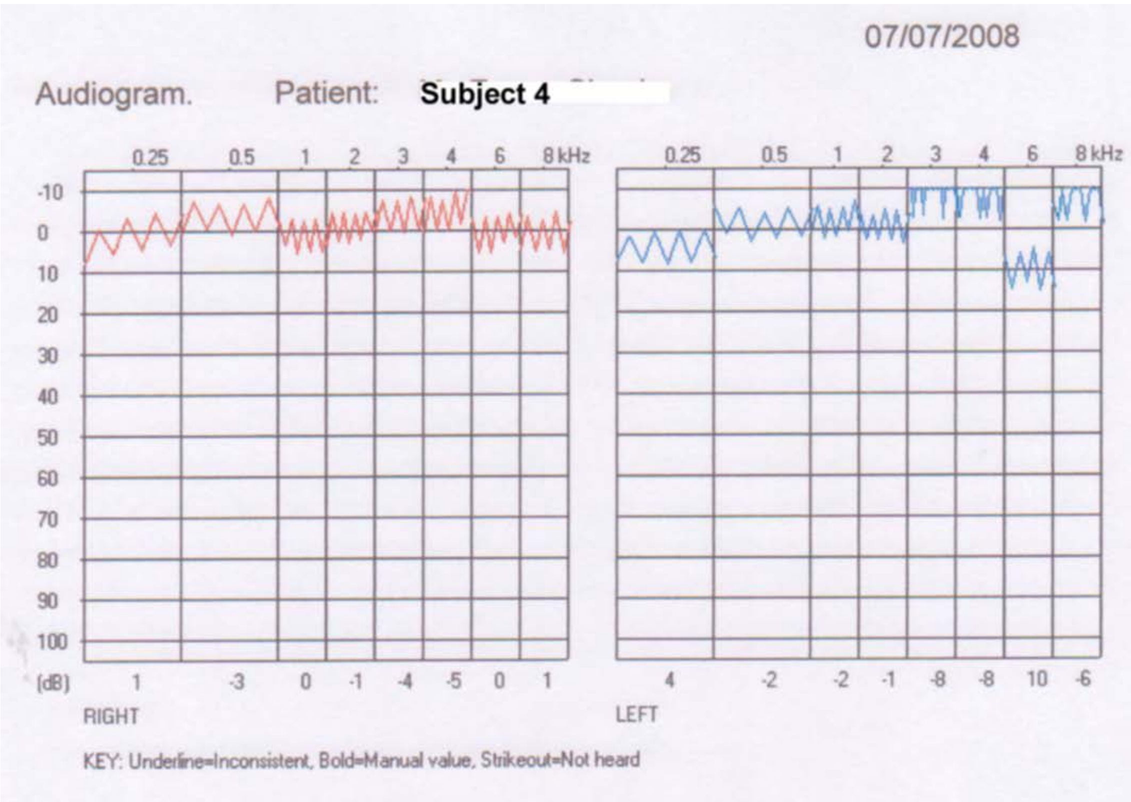
Step 10: Affix CE marking on your product and/or its packaging and accompanying literature as stated in the directive.

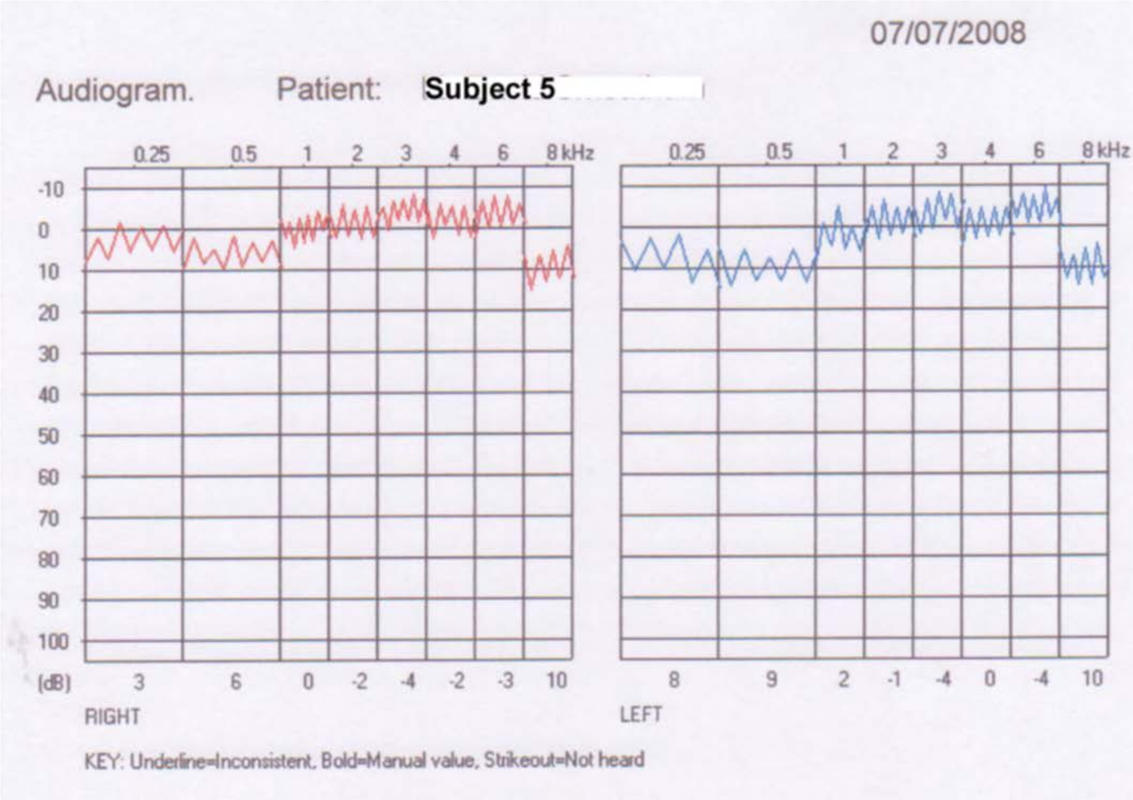
APPENDIX C – SUBJECT AUDIOGRAMS

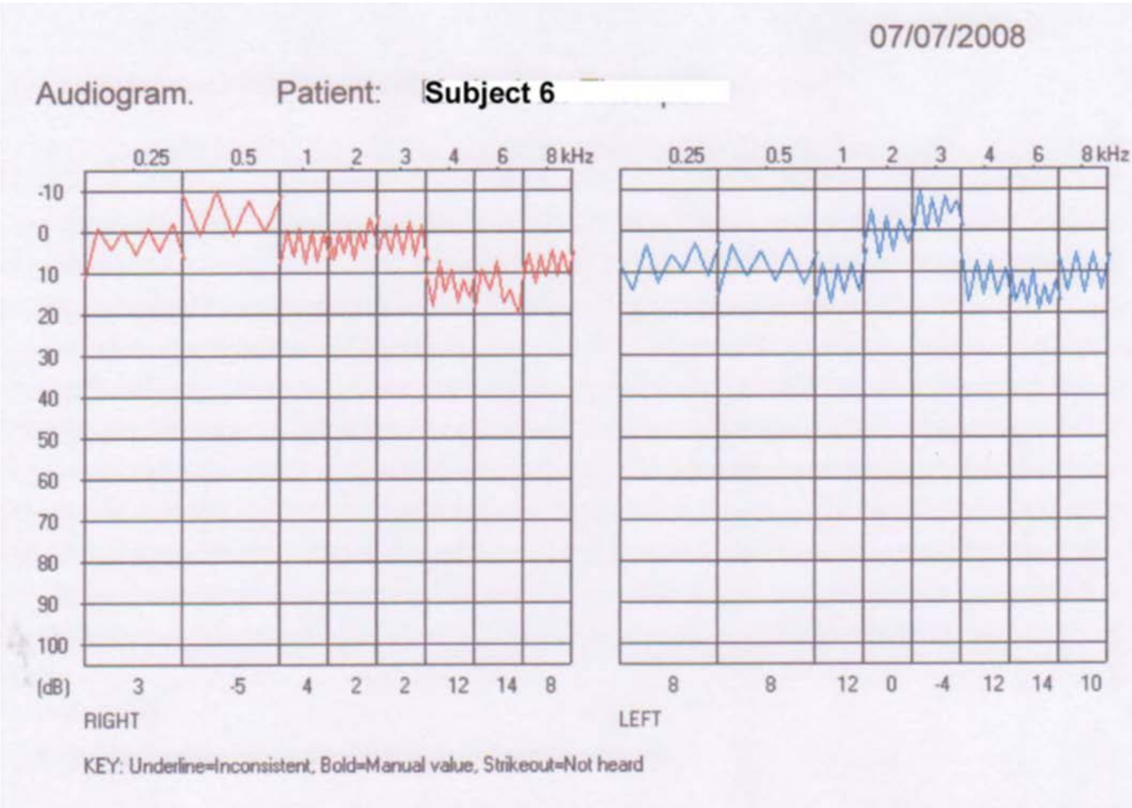


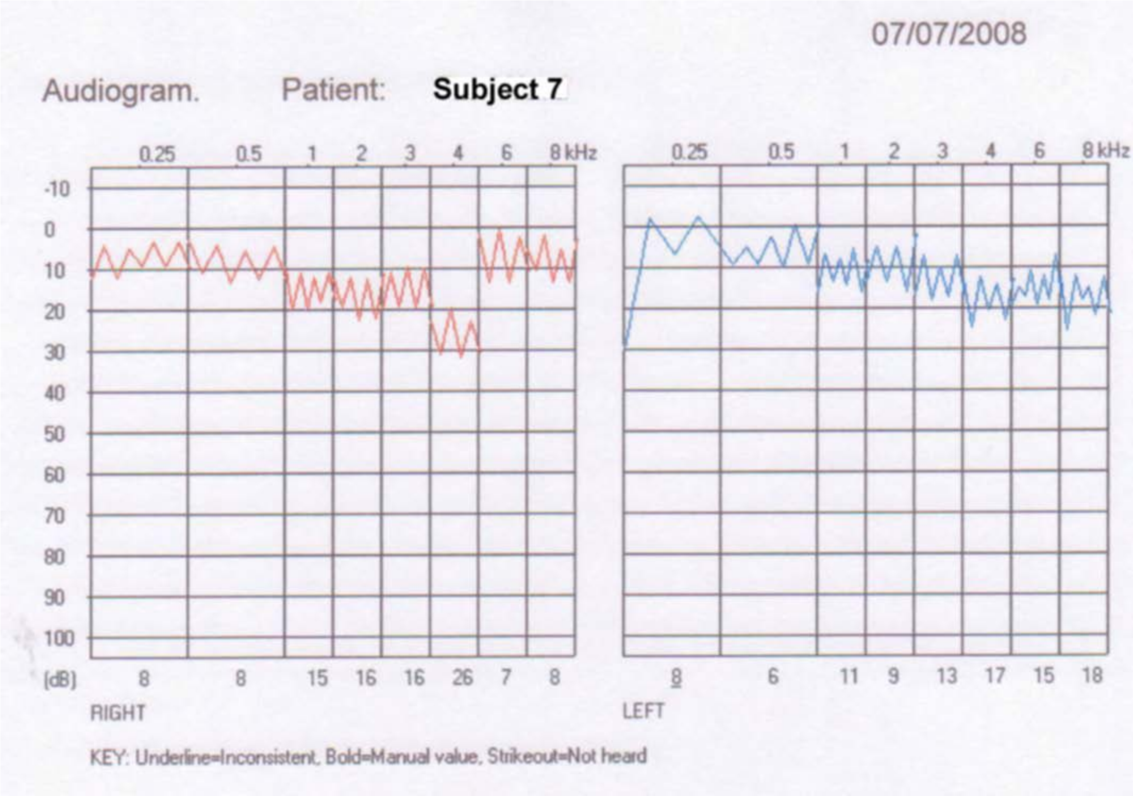



07/07/2008
Audiogram.
Patient: Subject 3
0.25 0.5 1 2 3 4 6 8 kHz
0.25 0.5 1 2 3 4 6 8 kHz
-10
0
10
20
30
40
50
60
70
80
90
100
(dB)
2 2 -1 0 -3 1 22 7
1 0 -2 -6 -9 11 14 2
RIGHT
LEFT
KEY: Underline=Inconsistent, Bold=Manual value, Strikeout=Not heard


07/07/2008
Audiogram.
Patient: Subject 4
0.25 0.5 1 2 3 4 6 8 kHz
0.25 0.5 1 2 3 4 6 8 kHz
-10
0
10
20
30
40
50
60
70
80
90
100
(dB)
1 -3 0 -1 -4 -5 0 1
4 -2 -2 -1 -8 -8 10 -6
RIGHT
LEFT
KEY: Underline=Inconsistent, Bold=Manual value, Strikeout=Not heard


07/07/2008
Audiogram.
Patient:
Subject 5
0.25 0.5 1 2 3 4 6 8 kHz
0.25 0.5 1 2 3 4 6 8 kHz
-10 0 10 20 30 40 50 60 70 80 90 100 (dB)
3 6 0 -2 -4 -2 -3 10
8 9 2 -1 -4 0 -4 10
RIGHT
LEFT
KEY: Underline=Inconsistent, Bold=Manual value, Strikeout=Not heard


07/07/2008
Audiogram.
Patient:
Subject 6
0.25 0.5 1 2 3 4 6 8 kHz
0.25 0.5 1 2 3 4 6 8 kHz
-10 0 10 20 30 40 50 60 70 80 90 100 (dB)
3 -5 4 2 2 12 14 8
8 8 12 0 -4 12 14 10
RIGHT
LEFT
KEY: Underline=Inconsistent, Bold=Manual value, Strikeout=Not heard



07/07/2008
Audiogram.
Patient:
Subject 7
0.25
0.5
1
2
3
4
6
8 kHz
-10
0
10
20
30
40
50
60
70
80
90
100
(dB)
8
8
15
16
16
26
7
8
RIGHT
8
6
11
9
13
17
15
18
LEFT
KEY: Underline=Inconsistent, Bold=Manual value, Strikeout=Not heard

APPENDIX D – ATTENUATION RESULTS

Model A – HSL measured attenuation in dB for individual subjects

Subject	Attenuation (dB) per frequency band (Hz)								H	M	L	SNR
	63	125	250	500	1k	2k	4k	8k				
Subject 1	26	24	20	28	22	22	16	22	18.9	21.2	21.8	21.2
Subject 2	20	18	24	24	24	22	30	18	22.1	23.6	22.9	23.9
Subject 3	10	4	-2	2	10	15	20	10	13.8	6.4	1.8	9.7
Subject 4	22	26	26	26	24	18	26	24	20.3	22.2	23.5	23.3
Subject 5												
Subject 6	18	22	22	11	22	22	31	20	22.8	17.2	15.9	20.5
Subject 7	22	22	20	20	14	14	32	26	16.6	15.5	16.9	18.4
Mean	19.7	19.3	18.3	18.5	19.3	18.8	25.8	20.0	19.1	17.7	17.1	19.5
Std Dev	5.0	7.3	9.3	9.2	5.4	3.4	6.0	5.2	3.1	5.8	7.4	4.7

Model B – HSL measured attenuation in dB for individual subjects

Subject	Attenuation (dB) per frequency band (Hz)								H	M	L	SNR
	63	125	250	500	1k	2k	4k	8k				
Subject 1	18	12	14	12	16	30	30	24	23.8	16.1	14.2	20.2
Subject 2	4	2	0	5	8	20	26	18	16.1	7.8	3.5	11.6
Subject 3	6	2	12	10	14	29	32	18	21.3	14.0	9.7	17.5
Subject 4	6	10	4	14	14	28	36	28	22.9	13.9	8.5	17.7
Subject 5	2	1	4	6	10	18	22	20	16.9	9.6	5.7	13.3
Subject 6												
Subject 7	6	10	8	14	14	20	46	28	20.8	14.9	11.4	18.6
Mean	7.0	6.2	7.0	10.2	12.7	24.2	32.0	22.7	20.3	12.7	8.8	16.5
Std Dev	5.1	4.6	4.9	3.6	2.7	4.9	7.7	4.3	2.9	3.0	3.5	3.0

Model C – HSL measured attenuation in dB for individual subjects

Subject	Attenuation (dB) per frequency band (Hz)								H	M	L	SNR
	63	125	250	500	1k	2k	4k	8k				
Subject 1	14	18	22	24	24	32	29	38	29.8	25.3	22.8	28.6
Subject 2	6	6	11	14	16	28	30	24	23.8	16.5	12.2	20.2
Subject 3	10	14	22	20	22	34	29	34	29.1	23.0	20.1	26.6
Subject 4	18	20	18	24	28	34	40	36	34.0	26.7	21.7	30.2
Subject 5	9	8	8	14	16	24	32	24	23.1	15.9	11.3	19.5
Subject 6	14	10	10	8	14	28	33	26	22.1	13.0	10.7	17.1
Subject 7	14	18	18	26	16	30	44	28	25.0	19.1	19.0	23.5
Mean	12.1	13.4	15.6	18.6	19.4	30.0	33.9	30.0	26.7	19.9	16.8	23.7
Std Dev	3.7	5.1	5.4	6.2	4.9	3.4	5.4	5.5	4.0	4.8	4.8	4.6

Model D – HSL measured attenuation in dB for individual subjects

Subject	Attenuation (dB) per frequency band (Hz)								H	M	L	SNR
	63	**125**	**250**	**500**	**1k**	**2k**	**4k**	**8k**				
Subject 1	0	0	2	2	3	16	14	26	11.3	4.4	2.7	8.5
Subject 2	8	0	-2	2	2	10	8	4	6.9	3.1	0.9	5.9
Subject 3	4	4	4	6	2	19	28	18	11.5	4.7	4.5	9.2
Subject 4	8	12	14	18	24	32	36	18	25.2	21.6	16.4	23.4
Subject 5	0	2	4	16	6	16	24	24	14.4	8.7	6.4	12.7
Subject 6	8	10	8	-1	12	26	34	14	16.4	5.8	4.0	9.9
Subject 7	4	0	4	-1	0	12	38	14	8.7	1.6	1.2	6.0
Mean	4.6	4.0	4.9	6.0	7.0	18.7	26.0	16.9	13.5	7.1	5.2	10.8
Std Dev	3.3	4.7	4.6	7.3	7.8	7.2	10.6	6.7	5.6	6.3	4.9	5.6

Model E – HSL measured attenuation in dB for individual subjects

Subject	Attenuation (dB) per frequency band (Hz)								H	M	L	SNR
	63	**125**	**250**	**500**	**1k**	**2k**	**4k**	**8k**				
Subject 1	14	16	18	20	21	32	34	36	29.1	22.2	19.6	26.2
Subject 2	10	6	8	12	10	28	32	26	19.5	12.1	9.9	16.4
Subject 3	14	24	14	18	22	30	38	40	29.3	21.4	17.7	25.2
Subject 4	8	18	16	24	20	32	40	40	28.9	22.1	19.0	26.2
Subject 5	11	12	12	17	18	29	40	32	26.4	18.8	15.0	22.7
Subject 6	4	3	4	0	4	26	29	20	13.1	4.3	3.0	8.7
Subject 7	16	10	12	15	10	20	54	22	18.3	12.7	12.4	16.9
Mean	11.0	12.7	12.0	15.1	15.0	28.1	38.1	30.9	23.5	16.2	13.8	20.3
Std Dev	3.8	6.7	4.4	7.1	6.4	3.9	7.5	7.7	6.0	6.3	5.5	6.1

APPENDIX E – KS-TEST RESULTS

<u>Table E.1. Summary of KS-test results</u>

The Kolmogorov-Smirnoff test was carried out to determine whether the HSL measured attenuation values were taken from an underlying "true distribution" of attenuation values that were the same as the manufacturers' distributions. Table E.1 contains the KS-test results.

Table E.1. Summary of KS-test results

Model	Statistical significance per frequency band (Hz)							
	63	**125**	**250**	**500**	**1000**	**2000**	**4000**	**8000**
A	n/a	8.01E-01	4.44E-01	4.25E-01	4.24E-01	5.33E-02	1.73E-02	3.29E-02
B	6.92E-04	3.96E-05	1.12E-05	7.08E-10	8.88E-15	3.52E-03	2.31E-03	5.60E-09
C	1.01E-06	7.89E-07	7.49E-08	5.88E-03	3.16E-04	5.13E-04	1.28E-03	1.60E-02
D	0.00E+00	1.52E-07	2.99E-06	4.06E-04	3.32E-06	7.01E-05	1.44E-02	7.94E-04
E	n/a	8.97E-06	1.93E-02	3.12E-02	1.17E-01	2.78E-01	7.06E-02	1.48E-01

'S' Attenuation values significantly different from manufacturers declaration at 99% confidence.
'NS' Attenuation values *not* significantly different from manufacturers declaration at 99% confidence.

<u>Figure E.1. The Dot Plot</u>

The dot plot is useful for determining where the HSL measured attenuation values lie in terms of the percentile of the declared attenuation. This is much simpler and clearer than the cumulative distribution plot in Figure E.2. It does not allow for comparison between the declared distributions.

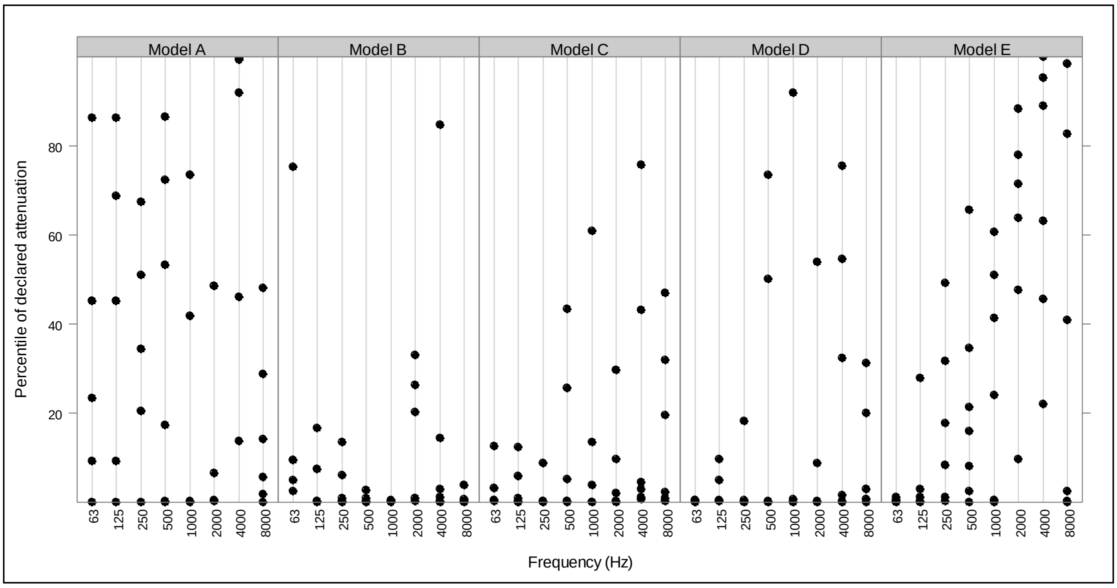


Figure E.1. Dot plot

Figure E.2. The cumulative distribution plot

For each earplug model, at each test frequency, the attenuation result for each subject is shown as a point on a normal distribution curve. The normal distribution is based on the manufacturer's declared attenuation and standard deviation. If the HSL measured attenuations were taken from the manufacturer's declared distribution, the points would be spread along the curve, with more points close to the middle. This plot also shows the difference between declared distributions - those with a higher mean are further to the right, and those with a lower standard deviation have a steeper curve.

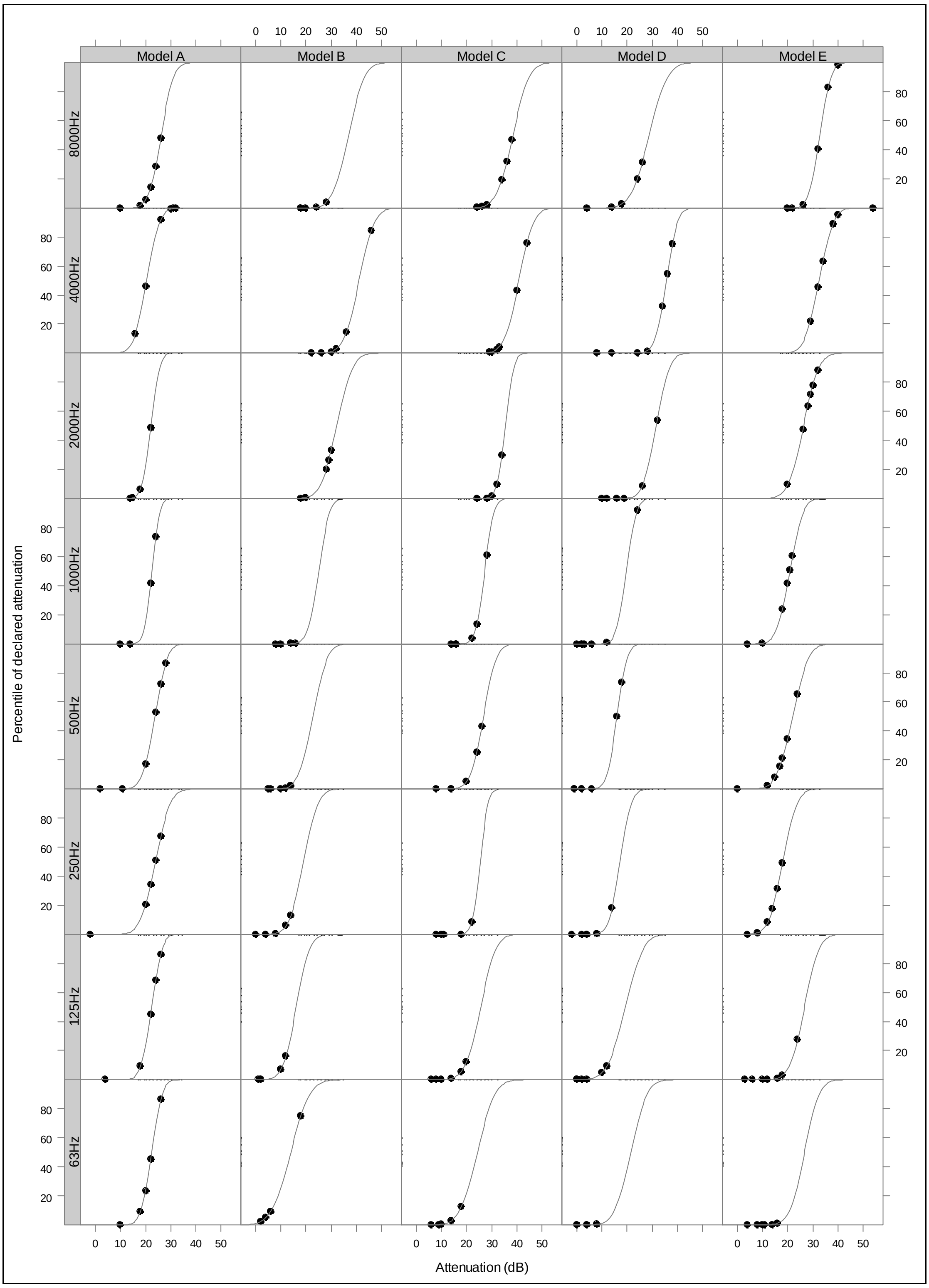


Figure E.2. Cumulative distribution function plots

Published by the Health and Safety Executive 08/09

Health and Safety Executive

Market surveillance of custom-moulded earplugs

Earplugs are available that are custom-moulded to the shape of an individual's ears. Such earplugs when used as personal protective equipment in the workplace can offer a longer life span, potential cost savings to employers and, it is often claimed, an improved level of protection and comfort compared to other forms of hearing protection. A study of a selection of CE-marked custom-moulded earplugs available in the UK was carried out in order to examine the protection provided by such devices, and to identify any influencing factors on protection, comfort and fit.

Five models of earplug were subjectively tested using either six or seven subjects. Apart from one poorly performing self-moulded earplug, the plugs provided attenuation (SNR values) in the range 16 to 24 decibels. Levels of protection for all plugs were lower than indicated by manufacturers, and statistical analysis suggested that three of the earplug models were not adequately represented by the manufacturer's attenuation data. There was no evidence to support the view that custom-moulded earplugs provide improved levels of protection compared to other forms of hearing protection. When checked against the labelling and information requirements of the relevant product standard, BS EN 352-2:2002, only one of the models completely satisfied the requirements of the standard. A variety of information was missing including attenuation data and fitting instructions.

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