EUHA Guideline

Custom-made earmoulds for hearing protection

Guideline 06-01

EUHA
Europäische Union der Hörgeräteakustiker e.V.

Preface

Noise is a significant phenomenon of our technology-driven society. Increased exposure to noise at the workplace as well as in private life may endanger or damage human health in many ways. Noise protection has therefore attained great importance for society. An essential component is immission control, which should ideally be effected by custom-made earmoulds for hearing protection. Custom-made protectors are superior to standard solutions as far as efficiency, wearing comfort, durability, and ease of care are concerned. Moreover, targeted use of construction design and acoustic filters contribute to optimising individual protection.

Aim:

By outlining working processes and techniques, this Guideline ensures the maintenance of a consistently high quality standard for fitting custom-made earmoulds for hearing protection. The particular case of "fitting hearing protection to hearing aid users" is dealt with in EUHA Guideline 02, "Hearing protection for hearing aid users".

Contents:

1. Requirements and professional qualification of operator

The technically correct and suitable provision of custom-made earmoulds for hearing protection may be relevant to health. It may therefore only be performed according to this Guideline if the corresponding requirements are met:

- Profession qualification that includes expertise in the areas of acoustics, medicine, material science, earmoulds, noise protection and noise protection regulations as well as practical skills in taking ear impressions and manufacturing and processing earmoulds. To guarantee optimum quality, such suitable provision according to this Guideline is to be performed by a hearing aid acoustician.
- Technical requirements for taking ear impressions:
  otoscope or other equipment suitable for optical inspection of tympanum, auditory canal and pinna; low-viscosity mould making materials and tools that permit maximum accuracy of shape.
- Space and technical requirements for expert fitting and optimisation of earmoulds for hearing protection: milling unit or polisher with drill, milling and polishing bits, protective equipment such as protective goggles, mask and hearing protectors, tube expanders, polishing materials, adhesives, solvents, lacquers, UV curing equipment.
- Space and technical requirements for functional testing.

2. Needs assessment and consultation

In order to be able to make sensible use of the whole range of suitable earmoulds for hearing protection, targeted needs assessment is required. This should essentially include:

- Type, level, frequency range and duration of the noise concerned
- Use (private, occupational – use as work protection: cf. item 6)
- Requirements concerning protection efficiency/attenuation provided by the earmoulds
- Requirements for the perception of sound signals
- Safeguarding wearing comfort (e.g. hardhat, sleep earmoulds, etc.)
- Further requirements (e.g. water resistance, cosmetics, etc.)

Based on these findings, needs-based consultation should be carried out subsequently, taking into account the following:

- Types and designs of earmoulds for hearing protection
- Materials and tolerance
- Acoustic filters
- Cosmetics
- Information on costs
- Sustainability – regular functional testing is required

3. Ear impression and lab manufacturing of earmoulds for hearing protection

The most important requirement for manufacturing adequate earmoulds for hearing protection is the availability of precision ear impressions of the outer ear. These are taken according to the regulations laid down in the occupational training profile for hearing aid acousticians (according to article 3, clause 14, of the training regulations in conjunction with no. 14 of the training provision plan). The procedure applied must be "non-deforming", using low-viscosity mould making materials. Ideally, a cartridge impression gun with mixing tips is employed where no cross-linking has occurred before the mould making material is injected into the auditory canal. If required, the raw impression must then be processed taking into account wearing comfort, cosmetics, and proper fit. Taking an ear impression is a hazardous skilled manual task that must only be performed by persons adequately qualified and authorised.

Earmoulds for hearing protection are manufactured in a laboratory specialising in earmoulds. Care should be taken that deformation caused by waxing or rigorous lacquering is definitely avoided. The procedures generally accepted for manufacturing may be used.

The earmoulds for hearing protection must be fitted with an ergonomically sound solution for removal (grip, handle, string).

The earmoulds for hearing protection must be labelled with a permanent characteristic: ear side (colour coding), ID number, or name.

4. Fitting and delivery

When the earmoulds are delivered, the customer is to be given detailed instructions on their use. Especially inserting and removing the earmoulds are to be demonstrated.

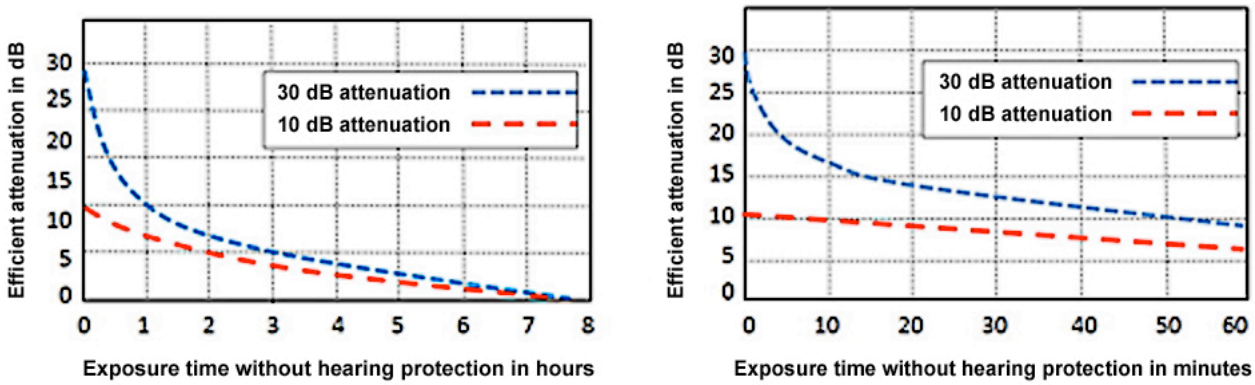
Using the ear impressions as a reference, fitting accuracy of the finished earmoulds is to be tested on the customer's ears. Wearing comfort and secure fit must also be checked.

The earmoulds must be delivered in an adequate container, accompanied by detailed instructions for use and care.

A functional test according to item 5 must be performed.

The instructions must explicitly make clear that efficient attenuation will significantly be reduced if the hearing protectors are not in place at all times as illustrated by the diagram below.

Efficient attenuation provided by hearing protection is reduced if not worn at all times



5. Functional test

In order to make sure that the desired effect is achieved, a person qualified for the task (cf. item 1) must perform functional testing upon delivery of the earmoulds for hearing protection.
At present, there is no metrological procedure that may be recommended in this Guideline without restrictions. As stipulated by the requirements laid down by the German statutory accident insurance (DGUV), metrological functional testing may be carried out either by determining the damping coefficient using audiometric methods, or by a (physical) tightness test.

Damping coefficient test:

- The damping coefficient test must be carried out according to the specifications given by the respective manufacturers.
- It may be performed in the free field or via headphones, with a view to determining the hearing threshold with and without hearing protection (if applicable, including filters).
- The difference between the value without and that with hearing protection equals the damping coefficient.
- PLEASE NOTE: *Due to the high level of ambient noise, which applies even in favourable conditions, an accurate determination of the hearing threshold in normal hearing listeners is hardly achievable. Unless carried out under optimum conditions present in an anechoic chamber, this procedure is subject to high inaccuracy. For this reason, its applicability is restricted, especially in the commercial sector where a great number of people have to be tested at the workplace.*

Physical tightness test:

- Before carrying out the tightness test, any filters have to be removed.
- Static air pressure is built up in the auditory canal via the existing opening.
- Unless there is a drop in pressure, one may assume that acoustic dampening is sufficient.
- An unconditional requirement for using this testing method is an intact tympanum.
- PLEASE NOTE: *There is the risk of tympanum perforation.*

6. Standards for the use in safety at work

Earmoulds for hearing protection are category 2 personal protective equipment (PPE) and may only be brought into circulation if accompanied by an EC type examination certificate. Additional requirements apply for the commercial use of earmoulds for hearing protection:

- Earmoulds for hearing protection are custom-made products. According to Directive 89/686/EEC and Section 8 of the Product Safety Act they must bear the CE mark.
- Earmoulds for hearing protection must pass a functional test upon delivery (within six months), the results of which must be documented.
- A repeat test and documentation must be performed at least every two years.
- Earmoulds for hearing protection must bear an unequivocal personal mark.
- The container must be labelled with the wearer's name.
- Instructions for use and care must conform to the requirements of commercial use.

7. Sources and references

- EC Directive 89/686/EEC
- BGR/GUV-R194
- Section 8 of the Product Safety Act (PPE), *PSA - 8. GSGV*
- Noise and Vibration Occupational Safety Regulation of 23 March 2010 (*TLRV Lärm*)
- "Hearing protection" guideline (BGI/GUV-I 5024) of the German statutory accident insurance
- BGR/GUV-R194 rules on safety and health at the workplace developed by the Employers' Liability Insurance Association of the German statutory accident insurance
- Accident prevention regulations
- Medicinal Products Act
- Ivar Veit: Technische Akustik, Vogel-Buchverlag (Würzburg, ISBN 978-3-8343-3282-0)
- Ulrich Voogdt: Otoplastik, vol. 2 of Wissenschaftliche Fachbuchreihe der Akademie für Hörgeräte-Akustik, 4th rev. ed. 2013

8. Authors

Working group for this Guideline:

- Prof. Dr.-Ing. Ivar Veit, University of Applied Sciences, Wiesbaden
- Beate Gromke, master craftswoman of hearing aid acoustics, Leipzig
- Erich Bayer, master craftsman of hearing aid acoustics, Munich
- Dipl.-Ing. Ulrich Voogdt, Academy of Hearing Aid Acoustics, Lübeck
- Eric Zimmermann, solicitor, Federal Guild of Hearing Aid Acousticians, Mainz
- Wolfgang Luber, master craftsman of hearing aid acoustics, Munich

Coordination and contact: Wolfgang Luber