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. Especially where hearing impairment is already present, hearing protection is of utmost importance. An essential component is immission control, which should ideally be effected by specific approaches in hearing aid fitting.

Aim:

By outlining working processes and techniques, this Guideline ensures the maintenance of a consistently high quality standard for providing hearing aid users with hearing protection. The basic principles of fitting individually tailored earmoulds for hearing protection are dealt with in EUHA Guideline 01.
1. Requirements and professional qualification of operator

The technically correct and suitable provision of individually tailored earmoulds for hearing protection may be relevant to health. It may therefore only be performed by trained hearing aid acousticians who are authorised to practice the trade. The admission requirements are identical to those that apply to standard hearing aid fitting.

2. Compatibility of fitting hearing aids and hearing protectors

If professionally fitted, hearing aids may also be worn in noise without the risk of hearing damage. However, when hearing systems are used in noise, apart from considering the increased sound pressure level, one has to take account of the exposure time and the fact that the auditory canal may not completely be sealed via the individually fitted earmould. Generally, there are special requirements for earmoulds. The two components, "hearing aid" and "earmould", must be looked at individually, and will therefore be dealt with separately in this Guideline.

If accurately designed and manufactured according to the specifications delineated in this Guideline, a hearing system can be used as hearing protection in the sense of personal protective equipment (PPE).
3. PPE requirements for earmould manufacturing and design

Hearing aids that are used as PPE must be equipped with earmoulds for hearing protection. Optimum fitting is extremely important for effective protection of hearing, which may only be accomplished by taking accurate in-ear impressions. The latter must therefore be taken by means of a "non-deforming" procedure, using low-viscosity mould making materials. Ideally, a mixing needle 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. Manufacturing is carried out by a laboratory specialising in earmoulds (cf. EUHA Guideline 01 – Individually tailored earmoulds for hearing protection). Care should be taken that deformation caused by waxing or rigorous lacquering is definitely avoided. The procedures generally accepted for manufacturing may be used; they are not restricted to certain methods. The design and material are selected with a view to achieving optimum results.

PLEASE NOTE: Additional vents or similar openings may only be placed in the earmould if they can be sealed in noise. They function as Helmholtz resonators, which means that noise below the resonant frequency (which may range between 100 Hz and 2000 Hz, depending on the design) is transmitted. Noise at a frequency equalling the resonant frequency is even amplified.

If the type of hearing loss renders a closed earmould uncomfortable, one should manufacture two separate earmoulds, one for use in noise and one for quiet settings. In this case, the hearing aid user should change the earmoulds as required.
4. **PPE functional test for earmoulds**

In order to make sure that the desired effect as PPE is achieved, functional testing must be performed after hearing aid fitting. 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 is performed with the hearing aids in place, but switched off.
- It is performed in the free field, with a view to determining the hearing threshold with and without hearing aids.
- The difference between the value without hearing aids and that with hearing aids in place, but switched off 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 listeners with only moderate hearing loss may be error-prone. This must be taken into account when selecting an adequate procedure.*

**Physical tightness test:**
- Before carrying out the tightness test, the BTE hearing aid must be removed (in the case of ITE systems, a tightness test may only be performed via a test channel).
- Air pressure is built up via the existing sound channel.
- 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.*
5. **PPE requirements for selecting and programming hearing aids**

BTE as well as ITE devices may have a protective function as part of the PPE. The hearing aids used should be equipped with at least two programs, one of which may be used as a "hearing protection program". The hearing protection program must be individually programmable, and should be positioned such that it is active as soon as the device is switched on. When programming the hearing aids, one should take account of the following:

- Depending on the duration of noise exposure, the maximum sound pressure level of the hearing aids must be limited such that an exposure level of 85 dB (A) over the course of eight hours is not exceeded.
- The limitation of the maximum sound pressure level is verified in situ.
- Compression systems and other technical features available are to be employed to transmit speech signals in residual dynamics such that basic communication is achievable even in noise.
- The noise program must be set such that the user may not make any changes.
- Danger signals must be perceptible even when the noise program is active.
- Regulations on the commercial use are available in BGR/GUV-R194, Section 3.3.11.
- **PLEASE NOTE:** Efficient hearing protection is drastically reduced if the devices are not worn at all times (if the hearing aids are removed in spite of continuing noise).

[Anm. d. Übers.: Abb. bitte aus Leitlinie 06-01 übernehmen.]
6. **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
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