


EUHA Guideline

Custom-made earmoulds for fitting hearing systems

Guideline 05-01

EUHA

Europäische Union der
Hörakustiker e.V.

EUHA Guideline		No. 05-01	 Europäische Union der Hörakustiker e.V. <small>Fachwissenschaftliche Organisation der Hörakustiker</small>
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Preface


Custom-made earmoulds are key components of modern hearing systems, as they determine to a large degree the benefit of such systems for individuals. Earmoulds affect many different aspects of hearing systems, from acoustic and audiological effectiveness and medical-anatomical design to practical handling and aesthetic concerns. The quality of custom-made earmoulds determines the benefit a patient gains from his or her hearing systems and thus customer satisfaction. Good, properly fitting earmoulds demonstrate the professional competence and the craftsmanship of the hearing aid acoustician.

Aim:

This Guideline aims at establishing a consistent high quality standard for sound delivery devices in hearing systems. It focuses on custom-made earmoulds for air-conduction hearing systems and cochlear implants (BTE, bimodal and EAS devices). Custom-made earmoulds for hearing protection are the dealt with in EUHA Guidelines 06-01 and 06-02.

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1. Requirements and qualification of earmould fitter

The production of quality custom-made earmoulds, which determine the sound quality that can be achieved with the connected hearing systems, is a highly specialised skill that requires proper training.

In Germany, companies that produce and supply devices for hearing systems must be registered with the trade association of hearing aid acousticians (§ 1 German Crafts and Trades Code). To qualify for registration, the company must be headed by a person who holds a master craftsman certificate or equivalent qualification.

According to the German Crafts and Trades Code, the production of earmoulds is one of the main tasks of hearing aid acousticians and deemed a potentially hazardous activity. The approved training programme for hearing aid acousticians covers the production of three-dimensional impressions of the outer ear and of earmoulds in a separate module, which also constitutes a section in the skilled crafts exam. Earmoulds are also a major subject of the master craftsman certificate for hearing aid acousticians.

In Germany, the costs for hearing aids and/or the earmoulds are generally covered by a statutory health insurer. To operate under this scheme, the company supplying the devices must be pre-qualified (§ 126 German Social Code V). Pre-qualification requires registration with the relevant trade association and the use of a suitably equipped dedicated workshop.

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2. Assessment of requirements, choice of shape and design


Modern hearing aids depend on reproducible physical conditions and custom-made earmoulds are able to meet the relevant audiological and acoustic requirements. This applies to all types of earmoulds, be they closed or open. The decision for a specific shape and type of earmould is made following a detailed assessment of the customer's needs. This assessment focuses on the following aspects:

2.1 Audiological diagnosis and acoustic effect

The findings of a detailed audiometric examination form the basis for the definition of the acoustic targets. Depending on the frequency curve and the dynamics of the hearing loss, and considering the technical features of the hearing system, the hearing aid acoustician chooses the type and shape of earmould that is most suitable to achieve the acoustic target.

The following main factors must be taken into account:

- The frequency transmission spectrum depends heavily on the length and diameter of the sound canal: the shorter and wider the sound channel, the better the transmission of high frequencies. This effect can be further enhanced by using horn systems.
- In RIC or ITE hearing aids, the position of the receiver, and thus the sound exit point, is close to the eardrum. This prevents undesired resonance and attenuation.
- Vents ensure pressure equalisation, ventilation, and acoustic optimisation. The acoustic system consisting of the vent and the residual ear canal volume determines the limit frequency below which there is virtually no amplification. At the limit frequency, resonance peaks occur while there are no such effects above this threshold.
- Open earmoulds provide maximum permeability in both directions. The acoustic effect changes the transmission characteristics of the hearing aid towards high frequencies while leading to loss of amplification across all frequencies. Even open systems require custom-made earmoulds, as they guarantee proper sound channelling as well as optimum wearing comfort and handling.

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- To prevent unwanted resonance, they can be combined with acoustic filters in the sound channel or vents. For best effect, the filter should be placed where the acoustic particle velocity is highest, i.e. near the sound channel exit.
- For feedback-free sound transfer, particularly with high initial sound pressure levels, earmoulds must seal the auditory canal properly. Preventing feedback by physical measures should take precedence over digital methods of feedback suppression, as occluding earmoulds cause less signal distortion, so that sound transmission is free of artefacts.

2.2 Anatomy

The anatomy of the ear determines the basic shape of the earmould.

2.3 Position and securing on ear

Custom-made earmoulds must keep the hearing system in place, minimising the risk of loss. For reproducible acoustic transmission of the sound, the actual hearing aid must be fitted at a defined position inside the ear.


2.4 Handling

The shape of the earmould must make it easy for the wearer to insert it correctly.

2.5 Material

The choice of the otoplastic material must be based on an anamnesis and an in-depth assessment of the customer's needs. Audiological aspects, the anatomy of the ear, the fixture of the device on the customer's ear, easy handling and medical concerns such as allergies must be taken into account.

The hearing aid acoustician ensures that only biocompatible earmoulds conforming to the German Medical Device Act (MPG) are used. Earmoulds can be made from hard, soft, or

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flexible materials or combinations thereof. Hard earmoulds generally consist of cold, hot, or UV polymerised acrylate, polyamide, or polycarbonate. Soft earmoulds are made from heat-vulcanised silicone, polyurethane, or soft acrylates of variable shore hardness.

The surface of earmoulds may be enhanced for extra grip and skin compatibility. They may be given antibacterial properties, for instance through plating with gold or rhodium and other special coatings. In some cases, earmoulds may be made from titanium, gold, ceramics, wood, or even stone.

2.6 Medical aspects


In the case of allergies to certain materials and under certain medical circumstances, special solutions might be required with regard to the shape and material of the earmould.

2.7 Wearing comfort

The acceptance of the hearing aid depends greatly on its wearing comfort. Designs with minimum skin contact that are light in weight and compact have proven most successful. Striking the right balance between wearing comfort and functionality is the main objective here.

2.8 Aesthetic considerations

Professional otoplastic advice always takes into account the aesthetic appearance of the earmould. Modern earmoulds are available in a variety of colours and sizes – from unobtrusive to extravagant and fashionable. Together with the wearer, the hearing aid acoustician must find a solution that meets both the functional and aesthetic requirements.

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3. Casting and production


Custom-made earmoulds must be based on precision casts of the outer ear known as ear impressions. These are made in a non-deformable material of a low viscosity. Before the ear impression is taken, the hearing aid acoustician might need to clarify a number of issues with the customer, including allergies or medical contraindications, and the outer ear, eardrum, concha and the retroauricular area must be examined by otoscopy. Before the ear impression compound is applied, the eardrum must be tamponaded. After the customer has been informed of the procedure, the compound is placed in the outer ear. This is best done using a mixing cannula that injects the material before it becomes chemically crosslinked.

Before the earmould is produced, the cast may need to be machined so that the hearing aid meets the defined requirements with regard to sound quality, aesthetics, wearing comfort and hold. Depending on the method of production, this may be done mechanically or by means of CAD.

4. Fitting custom-made earmould in customer's ear

In most cases, the custom-made earmoulds must be reworked to fit the customer's ear. During the fitting session, the following must be checked:

- Air exchange through auditory canal, taking into account audiological and technical aspects
- Length and shape of plug (cone shape, tight fit, etc.)
The earmould must not obstruct changes in the shape of the auditory canal resulting from jaw movements.
- Correct, permanent positioning of sound exit point and vent opening in auditory canal
- Proper sound guidance technology (sound tube, RIC, etc.), chosen and installed taking into account anatomical, acoustic, and aesthetic factors
- Wearing comfort (intrinsic sound properties, occlusion, tactile and acoustic sensation)


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- Aesthetics
- Secure fixture in ear canal and auricle

5. Measurement of acoustic transmission

The acoustic effect of custom-made earmoulds can only be validated by measurements performed as part of the fitting procedure. Suitable methods include in-situ measurement, percentile analysis, or loudness scaling. Such quantitative methods are indispensable for the proper fitting and fine-tuning of earmoulds. Otherwise, it is not possible to verify whether the hearing aid provides the frequency-specific and individually defined target gain, and the hearing aid acoustician would remain ignorant of the actual hearing situation of his or her customer.

(Also refer to EUHA Guidelines 04-01 "Hearing aid fitting using percentile analysis" and 04-05 "Schritte zur optimalen In-situ-Messung" – *available in German only*)

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6. Hygiene and care

The aspects of hygiene and care range from the production of the earmould in a specialist laboratory or at the hearing aid shop to the fitting session and subsequent cleaning and care of the hearing aid by the customer. According to the European Medical Devices Directive, Annex I, Section 8, medical devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user, or third parties. All applicable statutory regulations for hygiene and care must be strictly adhered to.


Ear impressions and earmoulds can be contaminated by microbes. To prevent infection, the Academy of Hearing Aid Acoustics in Lübeck recommends cleaning and disinfecting the earmoulds prior to finishing, shipping, or changing the sound tube in an ultrasonic bath or using a special cleaning product for earmoulds.

With ear impressions, this is done after the cotton wool or plastic foam pad has been removed.

When handling earmoulds, avoiding direct contact with hands is recommended, for instance by having the wearer place them on a tablet together with the hearing system. Before handing the earmoulds over to the wearer, they must be treated for the prescribed time with a suitable product in an ultrasonic bath.

For ultrasonic bath treatment, we recommend using a combined agent so that cleaning and disinfection can be completed in a single process. For details, refer to the hygiene plan of the Academy of Hearing Aid Acoustics in Lübeck.


The person wearing the hearing aid must regularly clean the device at home, and must therefore be instructed in the proper care of the devices and earmoulds. This is best done when the device is first fitted for the trial period, or at the latest during final consultation.

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7. Quality assurance and sustainability


Regular checks of the earmoulds make sure that the devices work properly and last for as long as possible. As hearing, the subjective perception of sound, and the shape of the outer ear tend to change over time, regular appointments for follow-up consultations should be arranged with the customer to ensure optimum benefit from the hearing system.

Should these check-ups reveal changes in the anatomy of the ear or to hearing, it might be necessary to produce and fit new earmoulds. A replacement might also be necessary if the earmould shows signs of wear, which is often the case with soft earmoulds.

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