

EUHA Guideline

Implanted hearing systems in auditory acoustics

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This guideline aims at structuring the work of hearing aid acousticians as providers of healthcare services for people with hearing impairments and users of implanted hearing systems.

Preamble

Hearing aid acousticians, implanting ENT clinics, resident ENT specialists, and all disciplines involved (= service providers) are ethically obligated to provide lifelong care and support for people with implanted hearing systems from the time a hearing loss is diagnosed.

Supporting the users of implanted hearing systems is an integral part of the hearing aid acoustician's work.

This task begins with advising and fitting conventional hearing systems and includes constantly weighing up additional surgical and fitting options. In direct exchange with all disciplines involved, hearing aid acousticians take an active part in lifelong aftercare for users of implanted hearing systems.

The basis of any activity in the field of caring for users of implanted hearing systems is the willingness of all service providers to collaborate. On the part of hearing aid acousticians working in this field, a specific qualification, a resulting level of activity, and participating in further training corresponding to this level offered by manufacturers, specialised clinics, or educational institutions authorised by the manufacturers of hearing implants are mandatory.

Professional competence and intensively practised collaboration of all those involved form the basis for successfully managing hearing in users of implanted hearing systems.

The structure developed here is a supplement to the Weißbuch Cochlea-Implantat (CI)-Versorgung [White paper on cochlear implant (CI) fitting and care] (https://cdn.hno.org/media/2021/ci-weissbuch-20-inkl-anlagen-datenblocke-und-zeitpunkte-datenerhebung-mit-logo-05-05-21.pdf).

Aims

This Guideline aims to ensure a consistently high standard of quality for hearing aid acousticians when supporting users of implanted hearing systems. Based on competence and experience, hearing aid acousticians provide neutral information on the possibilities and opportunities offered by implanted hearing systems. Hearing aid acousticians advise all patients with hearing profiles that deviate from WHO 1, 2 or 3 [1], or in the range of indications specified by the ENT specialist societies, or with pronounced air conduction and/or bone conduction components, on adequate options for care and fitting. As a provider of healthcare services, hearing aid acousticians ensure that users of implanted hearing systems receive adequate, close-to-home care as the number of patients increases.

EUHA Guideline		No. 08-01	
Title: Implanted hearing systems in auditory acoustics			EUHA Europäische Union der
Issued: 4 Oct 2022 Revised: Page 2 / 1		Page 2 / 10	Hörakustiker e.V.

Contents

ı	-	Requirements and professional qualifications	3		
	1.1	Hearing aid acousticians	3		
	1.2	Hearing aid acousticians with further training and hearing implant service	3		
	1.3	Hearing aid acousticians with further training as a hearing implant specialist			
		collaborating with a hospital or clinic	3		
2	I	dentifying and advising on alternative care options	4		
	2.1	Middle ear implants	4		
	2.2	Cochlear implants	4		
3	2	Services provided by hearing aid acousticians	5		
	3.1	Hygiene and care	5		
	3.2	Maintenance, servicing, and repairs	5		
	3.3	Regular checks	6		
	3.4	Adjustments/mapping/fitting	6		
4	ļ	Audiological checks	7		
5	Quality assurance and sustainability 7				
6	Sources and references 8				
7	Authors of this Guideline				

EUHA Guideline		No. 08-01	
Title: Implanted hearing systems in auditory acoustics			EUHA Europäische Union der
Issued: 4 Oct 2022 Revised: Page 3 /		Page 3 / 10	Hörakustiker e.V.

1 Requirements and professional qualifications

1.1 Hearing aid acousticians

As part of their training, hearing aid acousticians acquire knowledge about the hearing success to be expected, and about the limitations and contraindications of conventional care and fitting. Even during ongoing conventional fitting of hearing systems, alternative and/or additional fitting options are included in the consultation. Such consultation takes account of the customer's audiological and anatomical conditions, and is advisable when fitting with conventional hearing systems does not result in adequate hearing success.

1.2 Hearing aid acousticians with further training and hearing implant service

Based on their professional experience and the acquisition of advanced knowledge of indications for hearing implants, hearing aid acousticians take an active part in providing hearing implant service.

Thanks to regular seminars and training offered by the manufacturers of hearing implant systems, specialised clinics, or educational institutions authorised by the manufacturers, hearing aid acousticians are able to provide service to, and carry out maintenance and repairs for, users of implanted hearing systems.

1.3 Hearing aid acousticians with further training as a hearing implant specialist collaborating with a hospital or clinic

After completing their hands-on training in a hospital, clinic, or rehabilitation facility that provides CIs, hearing aid acousticians with a relevant qualification who have completed further training to become hearing implant specialists or CI acousticians receive comprehensive product and fitting training from the manufacturers of hearing implant systems, specialised clinics, or educational institutions authorised by the manufacturers. This forms the basis for adjustments to, and/or mapping/fitting of, cochlear implant systems in collaboration with the service providers.

EUHA Guideline		No. 08-01	
Title: Implanted hearing systems in auditory acoustics			EUHA Europäische Union der
Issued: 4 Oct 2022	Revised:	Page 4 / 10	Hörakustiker e.V.

2 Identifying and advising on alternative care options

Based on their specialist knowledge, experienced hearing aid acousticians interpret the audiological parameters collected, and are able to identify cases in which an alternative treatment option is advisable. In collaboration with all service providers concerned and the patient, hearing aid acousticians advise on alternative care options.

The indication areas and potential range of application of hearing implant solutions currently available on the market overlap. Hearing aid acousticians provide information from their point of view in order to support patients in taking a decision.[2]

Together with the attending ear, nose and throat specialist, and taking into account the findings of all disciplines involved, the patient will take the decision as to which type of fitting will be used. Hearing aid acousticians are required to exchange patient data with service providers in accordance with the current European and national data protection guidelines.[6]

2.1 Middle ear implants

As a rule, the indication for an implantable hearing system applies in patients who, for medical or audiological reasons, cannot be fitted with conventional hearing systems and for whom one may expect an implantable hearing system to provide permanently better hearing.[3]

This may apply in the case of:

- moderate to severe sensorineural hearing loss,
- conductive hearing loss,
- combined hearing loss,
- asymmetric hearing loss, e.g. single-sided deafness (SSD),

taking account of the current literature and the indication matrix of the manufacturer and/or the specific function of the respective system.

In any event, considering in the indication matrix innovations in technology that may allow an extension of the indication is mandatory.

2.2 Cochlear implants

As a rule, the indication for cochlear implantation applies in patients with moderate to severe sensorineural hearing loss and patients with deafness in one or both ears which cannot be adequately compensated for by fitting conventional hearing systems or employing surgical measures, and where one may expect cochlear implants to provide adequate hearing and speech intelligibility in background noise.

EUHA Guideline		No. 08-01	
Title: Implanted hearing systems in auditory acoustics			EUHA Europäische Union der
Issued: 4 Oct 2022 Revised: Page 5 / 10		Hörakustiker e.V.	

If the indication is for both sides, implantation on both sides is recommended.[4]
A prerequisite for implantation is an intact auditory nerve (part of medical diagnostics).
If these basic conditions are met, the hearing aid acoustician, collaborating with the attending ENT specialists and all disciplines associated, provides information about the alternative treatment option with a cochlear implant. Updates to indication criteria and technical developments are directly incorporated into the process.

3 Services provided by hearing aid acousticians

3.1 Hygiene and care

This field includes all services provided in the hearing aid shop as well as instructions on cleaning and care of the components of the hearing system to be carried out by the users in their daily routine. Medical devices and associated manufacturing processes must be designed in such a way that risks for patients, users, and third parties are excluded, or reduced, as far as possible. This also applies to risks from contamination and a lack of hygiene. To ensure trouble-free operation when such devices are used as intended, and over the expected service life, the manufacturer must provide specifications for cleaning and care of the devices which users must comply with – this, of course, also applies to the service provided by hearing aid acousticians.[5]

At regular intervals, users of implanted hearing systems should themselves carry out the cleaning and care required. To ensure this, hearing aid acousticians are actively involved in adequately educating users of implanted hearing systems.

3.2 Maintenance, servicing, and repairs

Hearing aid acousticians provide information and advice on all general questions concerning the speech processor, and assistance on the information offered by manufacturers and service providers regarding specific questions.

Hearing aid acousticians are a local point of contact for customers to

- purchase implant batteries, microphone covers, wearing parts and consumables,
- obtain compatible accessories such as wireless remote microphone systems, Bluetooth connections, inductive connections, telephones and accessories, remote controls, sports accessories, water protection sleeves,
- have a three-dimensional ear scan performed for the production of earmoulds, holding and support elements.

EUHA Guideline		No. 08-01	
Title: Implanted hearing systems in auditory acoustics			EUHA Europäische Union der
Issued: 4 Oct 2022 Revised: Page		Page 6 / 10	Hörakustiker e.V.

3.3 Regular checks

As part of aftercare and at the scheduled intervals, hearing aid acousticians carry out technical checks of the speech processor, the accessories, and any other external components that may be present. During this process, hearing aid acousticians must adhere to the specifications defined by the respective manufacturer.

3.4 Adjustments/mapping/fitting

Hearing aid acousticians fit middle ear implants at any time during the fitting process upon the instructions given by the manufacturer and based on the agreements that are in place with the service providers.

Upon the instructions given by the manufacturer, specialised clinics, or educational institutions authorised by the manufacturers, and based on the agreements that are in place with the service providers, hearing aid acousticians with further training who have completed advanced training as an implant specialist or CI acoustician,

- determine MCL and THR values in cochlear implants,
- perform scaling and balancing,
- modify or optimise hearing programs,
- adjust contralateral fitting options in bimodal mode,
- and adjust acoustic components for electroacoustic stimulation (EAS, hybrid).

Hearing aid acousticians perform quality checks, examine electrophysiological parameters, and collect speech test data on a regular basis to ensure that implanted hearing systems function properly.

The methods used to compare parameters are to be agreed, and results shared, with the service providers. A common database is a prerequisite to assess and discuss significant deviations, and to adjust the relevant parameters.[6]

When replacing speech processors (upgrades), hearing aid acousticians document the hearing success achieved and, based on the prescription issued by the ENT specialist, apply for direct payments from the respective cost bearers.

In coordination with a clinic or hospital, hearing aid acousticians with further training as hearing implant specialists transfer or convert the settings/MAP for the new speech processor, inform the

EUHA Guideline		No. 08-01	
Title: Implanted hearing systems in auditory acoustics			EUHA Europäische Union der
Issued: 4 Oct 2022	Revised:	Page 7 / 10	Hörakustiker e.V.

clinic or rehabilitation facility about the progress, and train customers on how to use the new technology.

4 Audiological checks

In accordance with the white paper on CI care and fitting and with the agreements in place with the service providers, hearing aid acousticians perform measurements for telemetry, inflation curves, loudness scaling, and speech tests to monitor success. They also provide remote support and technical aftercare services.

5 Quality assurance and sustainability

Regular monitoring of implanted hearing systems ensures long-term and targeted care and fitting. Care and service providers are required to share the results of the follow-up visits on a regular basis – even without an adverse or undesirable event. Since anatomy, hearing ability, and subjective reactions may change, users are at any time free to approach doctors, providers of medical aids, members of other specialist fields, or manufacturers and distributors to discuss any adverse event and/or to have an exchange initiated. In coordination with the service providers, hearing aid acousticians adjust the system as a whole, or initiate measures to optimise or renew external components as well as to train users. This ensures that users of implanted hearing systems receive adequate care over the long term.

[1] Cf. WHO World Report on Hearing 2021

[2] Cf. AWMF-Leitlinie S017/73

[3] Cf. Lenarz et al., 1998, Tjellstöm & Granström, 1994, AWMF Leitlinie S017/73

[4] Cf. Laszig et al., AWMF-Leitlinie S017/73, Weißbuch Cochlea-Implantat-Versorgung

[5] Cf. MDR, Annex I, Section 8

[6] Cf. GDPR, Ch. 2, Art. 5-11

EUHA Guideline		No. 08-01	
Title: Implanted hearing systems in auditory acoustics			EUHA Europäische Union der
Issued: 4 Oct 2022 Revised: Page 8 / 10		Page 8 / 10	Hörakustiker e.V.

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EUHA Guideline		No. 08-01	
Title: Implanted hearing systems in auditory acoustics			EUHA Europäische Union der
Issued: 4 Oct 2022	Revised:	Page 9 / 10	Hörakustiker e.V.

7 Authors of this Guideline

Head of the EUHA Expert Group: Eva Keil-Becker, EUHA Vice President, master craftswoman of hearing aid acoustics, hearing implant specialist, Becker Hörakustik, Koblenz

Eberhard Aigner, master craftsman of hearing aid acoustics, hearing implant specialist, iffland hören, Ulm

Prof. Dr. med. Anke Lesinski-Schiedat, medical head of the German Hearing Center (DHZ) at the ENT Clinic, MHH, Hanover

Monika Mayer, master craftswoman of hearing aid acoustics, hearing implant specialist, Hörgeräte Seifert, Planegg

Michael Willenberg, Dipl.-Kfm. (FH), master craftsman of hearing aid acoustics, hearing implant specialist, Gromke Hörzentrum, Leipzig