

## **EUHA-Guidelines**

Implantable Hearing Systems within Acoustician Care)

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Title: Implanted Hearing aid	s in the Hearing acoustics		EUHA Europäische Union d
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It is a structuring of the work of the hearing care professional as a provider of health services for people with hearing disorders and users of implanted hearing systems.

#### Preamble

Audiologists, implanting ENT clinics, registered ENT doctors and all disciplines involved (= service providers) have the ethical obligation to provide and accompany people with implanted hearing systems throughout their lives from the beginning of hearing loss.

The accompaniment of users of implanted hearing systems is an integral part of the work of the audiologist.

This task begins with the consultation and fitting of conventional hearing systems and involves the constant consideration of complementary surgical options and care options. In direct exchange with all disciplines involved, hearing care professionals actively participate in lifelong follow-up care for users of implanted hearing systems.

The basis of every activity in the field of care for users of implanted hearing systems is the willingness of all service providers to coordinate. On the part of the hearing clinicians working here, a specific qualification, a consequent level of activity and further training corresponding to this level by the manufacturers, specialized clinics or educational institutions of hearing implants authorized by the manufacturer is mandatory.

Professional competence and intensive cooperation of all participants form the basis for the hearing success of users of implanted hearing systems.

The structuring developed here is complementary to the White Paper Cochlear Implant (CI) Care (https://cdn.hno.org/media/2021/ci-weissbuch-20-inkl-anlagen-datenblocke-und- dates-data-collection-with-logo-05-05-21.pdf).

#### Goals

This guideline aims at a consistently high standard of quality for hearing care professionals in the company of users of implanted hearing systems. On the basis of competence and experience, hearing care professionals provide neutral information about the possibilities and opportunities of implanted hearing systems. Auditory users show adequate treatment options to all patients with hearing profiles that have so far deviated from WHO 1, 2 or 3 [1] or in the indication spectrum designated by the ENT societies or in the case of pronounced airflow and/or bone conduction components. As a provider of health services, the audiologist ensures the qualitatively adequate, local care of users of implanted hearing systems with increasing patient numbers.

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# 1 Requirements and professional qualifications Requirements and professional qualifications

#### 1.1 Hearing acoustics

As part of their training, hearing care professionals acquire knowledge about the expected hearing success as well as the limits and contraindications of conventional care. Even during an ongoing conventional hearing aid treatment, alternative and/or additional supplementary care options are incorporated into the consultation. This is done with special consideration of audiological and anatomical conditions and in the absence of adequate hearing success with conventional hearing systems.

#### 1.2 Hearing acoustics with training and hearing implant service

With professional experience and the acquisition of advanced knowledge of indications of hearing implants, hearing care professionals are actively involved in hearing implant service.

With regular training and education by the manufacturers of hearing implant systems, specialized clinics or educational institutions authorized by the manufacturer, hearing care professionals are able to perform service, maintenance and repairs for users of implanted hearing aids.

## 1.3 Hearing care professional with training to become a hearing implant specialist in cooperation with a clinic

Hearing care professionals with further training and completed further training as hearing implant specialists/CI acousticians receive comprehensive product and fitting training from the manufacturers of Hearing implant systems, specialized clinics or manufacturer-authorized educational institutions. This forms the basis for adaptations/mapping/fitting of cochlear implant systems in coordination with the service providers.



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#### 2 Identification and demonstration of alternative supply options

On the basis of his specialist knowledge, the experienced audiologist interprets the audiological characteristics collected and recognizes cases in which an alternative treatment option is indicated. In consultation with all service providers and the patient, the audiologist points out alternative care options. The indication areas and possible applications of the hearing implant solutions currently available on the market overlap. The audiologist provides information from his point of view in order to support the patient's decision-making basis. [2]

The decision as to which type of care is used is determined by the patient together with the treating ear, nose and throat doctors, taking into account the findings of all disciplines involved.

Hearing care professionals exchange patient data with healthcare providers in accordance with current European and national data protection guidelines. [6]

#### 2.1 Middle ear implants

The indication for an implantable hearing system usually exists in patients who cannot be provided with conventional hearing systems for medical or audiological reasons and for whom an implantable hearing system can be expected to have permanently improved hearing.[3]

This may apply to:

- moderate to profound sensorineural hearing loss,
- Conductive hearing loss,
- combined hearing loss,
- asymmetric hearing loss, e.g. B. unilateral deafness (SSD)

taking into account the current literature and the indication matrix of the manufacturers / the purpose of the respective system.

In any case, innovations in the technology must be taken into account in the indication matrix, which may make it possible to extend the indication.

#### 2.2 Cochlear implants

The indication for cochlear implantation is i. d. R. in moderate to deafness, sensorineural hearing loss and in the case of deafness of one or both ears, which cannot be adequately compensated by conventional hearing systems or surgical measures and in which or

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who can be expected with cochlear implants sufficient hearing and speech understanding in background noise?

If indicated on both sides, bilateral implantation is recommended. [4] Prerequisite is an intact auditory nerve (part of medical diagnostics).

If these basic conditions are met, the audiologist informs in cooperation with the treating ENT doctors and all accompanying disciplines about the alternative treatment option with a cochlear implant. Updates to indication criteria and technical developments flow directly into the process.

#### 3 Services of the hearing care professional

#### 3.1 Hygiene and care

This area includes all services in the hearing aid shop as well as instruction in cleaning and care of hearing system components by users in their everyday lives.

Medical devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible risks to patients, users and third parties. This also applies to risks from contamination and lack of cleanliness. In order to ensure proper operation in accordance with the intended use and over the intended service life, the manufacturer must therefore specify the cleaning and care of the devices, which must be adhered to by the user – this of course also applies to the service provided by the audiologist. [5] Users of implanted hearing systems should carry out the necessary cleaning and care work independently at regular intervals. To ensure this, the hearing care professional is actively involved in the instruction of users of implanted hearing systems.

#### 3.2 Maintenance, service, repairs and servicing

Hearing care professionals provide information and advice on all general questions about speech processors, provide assistance and mediate on information offered by manufacturers and service providers on specific questions.

Hearing care professionals are a contact point close to home

- for the purchase of implant batteries, microphone covers, wear and consumables,
- the purchase of compatible accessories such as wireless acoustic transmission systems (DAÜ), Bluetooth connections, inductive connections, telephones and accessories, remote controls, sports accessories, water covers,

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 for three-dimensional ear impressions for the production of earmolds, holding and support plastics.

#### 3.3 Regular checks

As part of the aftercare, the audiologist carries out the technical examination of the speech processor, the accessories and, if necessary, the speech processor within the scheduled intervals. other existing external components. For this purpose, the specifications of the respective manufacturer must be complied with.

#### 3.4 Adaptation/Mapping/Fitting

Hearing care professionals fit middle ear implants at any time after instruction by the manufacturer and in accordance with the agreements with the service providers.

Hearing care professionals with further training and completed further training as implant specialists/CI acousticians investigate after instruction by the manufacturers of hearing implant systems, specialized clinics or educational institutions authorized by the manufacturer and in accordance with the agreements with the service providers

- MCL and THR values for cochlear implants,
- perform scaling and balancing,
- modify or optimize hearing programs.
- adapt contralateral supply options in bimodal operation,
- and tune acoustic components in electroacoustic stimulation (EAS, hybrid).

With quality controls, the testing of electrophysiological parameters and the regular collection of speech test data, hearing care professionals ensure the proper functioning of implanted hearing systems.

The methods used for comparative parameter tuning are to be coordinated and exchanged with the service providers. A common database allows the assessment of significant deviations, their discussion and the adjustment of corresponding parameters. [6] When renewing speech processors (upgrade), hearing care professionals document hearing success and apply for reimbursement from the respective payers in accordance with the ENT medical prescription.

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Hearing care professionals with further training as a hearing implant specialist in accordance with a clinic transmit/convert the settings/MAP for the new speech processor, inform the clinic/rehabilitation facility about the progress and instruct the user in the new technology.

#### 4 Audiological check

Hearing care professionals take measurements of telemetry, inflation curves, loudness scaling, speech tests to monitor success in accordance with the white paper on CI care and the agreements with the service providers and provide services in remote support and technical aftercare.

#### 5 Quality assurance and sustainability

Regular monitoring of implanted hearing systems ensures sustainable and targeted care. The results of the follow-up visits are to be regularly exchanged between supplying providers – even without *adverse event*. Since anatomy, hearing and subjective sensations can change, users have the opportunity to approach doctors, providers of remedies and aids, members of other disciplines or manufacturers and distributors at any time of their own choice, initiating the exchange/discussion of the *adverse event*. In coordination with the service providers, the audiologist adapts the overall system or initiates the optimization/renewal/instruction of the external components. This ensures sufficient care for users of implanted hearing systems in the long term.

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

<sup>[1]</sup> Vgl. WHO World Report on Hearing 2021

<sup>[2]</sup> Cf. AWMF Guideline S017/73

<sup>[3]</sup> See Lenarz et al., 1998, Tjellstöm & Granström, 1994, AWMF Guideline S017/73

<sup>[4]</sup> See Laszig et al., AWMF Guideline S017/73, White Paper Cochlear Implant Care

<sup>[5]</sup> See MDR, Annex I, Section 8

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