INTERNATIONAL STANDARD

ISO 21388

First edition
2020-03

Acoustics — Hearing aid fitting management (HAFM)

Acoustique — Gestion des appareils de correction auditive

Reference number
ISO 21388:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 43, *Acoustics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The World Health Organisation (WHO) estimates that there are 360 million people with hearing impairment, approximately 5,3 % of the world population[22]. Hearing aids (HAs) are one of the most widely-used treatment options for people with a hearing loss[39][40]. For the proper use of HAs, hearing aid fitting management (HAFM) is a crucial issue for manufacturers, practitioners, hearing aid professionals and especially for HA users[39][42][43]. Individually optimized outcome of HA use is supported by comprehensive HA fitting protocols[42] and the impact of “poor fit and comfort” can lead to non-compliance, HA return[43] and additional hearing loss with over-amplification. Accordingly, the whole process of HA fitting should be optimized to achieve functional benefits, user satisfaction and cost-effectiveness.

Two observations are important to take into account when developing an HAFM standard. Firstly, the term "hearing aid fitting" is widely used[16][44]–[46] among service providers and industry sectors. Secondly, it has potentially conflicting interpretations: while guidelines for HA fitting have been written to tackle these issues by various national and professional bodies[17][18][23]–[32][34]–[37][47][48], many jurisdictions are still not covered worldwide and there is a need to promote a more common understanding of the HA fitting process. It is likely that different understanding of fitting has led to non-uniform care, outcome variability and, in many cases, dissatisfaction with the use of HAs.

The main purpose of this document is thus to provide a general framework for HAFM including the pre- and post-fitting stages to make it more explicit and transparent so that all related tasks, including professional services, administration and financial aspects can be systematized. The overall objective is to achieve the best possible hearing rehabilitation, which can only be accomplished through adequate knowledge, training and skills of the professional and a systematic approach to HA fitting in close collaboration with the client. The general framework of HAFM in this document is divided into six stages (client profile, counselling, hearing aid fitting, verification and validation, post-fitting counseling, and follow-up) based on the common practices of hearing aid professionals, and as recommended by various pre-existing guidelines.

By dividing the hearing aid fitting process into stages, HAFM service providers can systematically identify and administer the service components needed for high service quality, user satisfaction, client-centered services, client self-efficacy and compliance rates with HAs (e.g. consistently using HAs and attending follow-up appointments). The stages focus on the components of the framework to achieve high rehabilitation outcomes such as communication skills, speech intelligibility, perception of the acoustic environment, comfort for the HA users and sound quality. In addition, this document can be a basis for making cost assessments for each stage or component, which can help improve public health funding systems. Another possible application is to use this document as a minimum basis for the development of professional training programs in HAFM.

Acoustics — Hearing aid fitting management (HAFM)

1 Scope

This document applies to hearing aid fitting management (HAFM) services offered by hearing aid professionals (HAP) when providing benefit for their clients. The provision of hearing aids relies on the knowledge and practices of a hearing aid professional, to ensure the proper fitting and adequate service in the interest of the client with hearing loss.

This document specifies general processes of HAFM from the client profile to the follow-up through administering, organising and controlling hearing aid fitting through all stages. It also specifies important preconditions such as education, facilities and systems that are required to ensure proper services.

The focus of this document is the services offered to the majority of adult clients with hearing impairment. It is recognized that certain populations with hearing loss such as children, persons with other disabilities or persons with implantable devices can require services outside the scope of this document. This document generally applies to air conduction hearing aids and for the most part also to bone conduction devices.

Hearing loss can be a consequence of serious medical conditions. Hearing aid professionals are not in a position to diagnose or treat such conditions. When assisting clients seeking hearing rehabilitation without prior medical examination, hearing aid professionals are expected to be observant of symptoms of such conditions and refer to proper medical care.

Further to the main body of the document, which specifies the HAFM requirements and processes, several informative annexes are provided. Appropriate education of hearing aid professionals is vital for exercising HAFM. Annex A defines the competencies required for the HAFM processes. Annex B offers a recommended curriculum for the education of hearing aid professionals. Annex C is an example of an appropriate fitting room. Annex D gives guidance on the referral of clients for medical or other specialist examination and treatment. Annex E is a recommendation for important information to be exchanged with the client during the process of HAFM. Annex F is a comprehensive terminology list offering definitions of the most current terms related to HAFM.

It is the intention that these annexes be helpful to those who wish to deliver HAFM of the highest quality.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8253-1, *Acoustics — Audiometric test methods — Part 1: Pure-tone air and bone conduction audiometry*

ISO 8253-2, *Acoustics — Audiometric test methods — Part 2: Sound field audiometry with pure-tone and narrow-band test signals*

ISO 8253-3, *Acoustics — Audiometric test methods — Part 3: Speech audiometry*

IEC 60118-7, *Electroacoustics — Hearing aids — Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes*

IEC 60645-1:2017, *Electroacoustics — Audiometric equipment — Part 1: Equipment for pure-tone and speech audiometry*

IEC 60645-5, *Electroacoustics — Audiometric equipment — Part 5: Instruments for the measurement of aural acoustic impedance/admittance*

IEC 61669, *Electroacoustics — Measurement of real-ear acoustic performance characteristics of hearing aids*

International Standard Classification of Education, ISCED. United Nations Educational, Scientific and Cutural Oganization, 2011, ISBN 978-92-9189-123-8, http://uis.unesco.org/sites/default/files/documents/international-standard-classification-of-education-isced-2011-en.pdf

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
auditory dynamic range
difference between the *hearing* (3.7) threshold and the uncomfortable loudness level (UCL)

3.2
client
person with *hearing loss* (3.8) being serviced by a *HAP* (3.13)

3.3
client profile
comprehensive record of a *client's* (3.2) auditory functionality, social situation, activity opportunities, needs and expectations as well as a client's audiological and medical history

3.4
ear impression
representation of the three-dimensional geometry of the relevant part of the concha and ear canal

3.5
fine-tuning
adjustment of the *hearing aid system* (3.10) to best match the needs and preferences of the *client* (3.2)

3.6
fitting system
set of devices typically comprising a computer, fitting software and a programming interface used to adjust *hearing aids* (3.9)

3.7
hearing
manner in which a person detects, discriminates, identifies and cognitively processes sounds

3.8
hearing loss
reduction of the *hearing* (3.7) ability

3.9
hearing aid
wearable electroacoustic instrument intended to process sounds in order to compensate for *hearing loss* (3.8)

Note 1 to entry: Hearing aids are medical devices and comply with the requirements of IEC 60601-2-66.

3.10
hearing aid system
customized structure consisting of one or two *hearing aids* (3.9), earmoulds and related components such as a remote control or interfaces to other information or communication systems

3.11
hearing aid fitting
systematic procedure for individualizing and optimizing a *hearing aid system* (3.10) to compensate for *hearing loss* (3.8)

3.12
hearing aid fitting management
HAFM
systematic process to administer, organise and control *hearing aid fitting* (3.11) through all stages

3.13
hearing aid professional
HAP
person who is appropriately trained and has proven competency in professionally assessing hearing, selecting, fitting and delivering *hearing aid systems* (3.10) and rehabilitation services to persons with *hearing loss* (3.8)

3.14
hearing rehabilitation
systematic process for improving functional hearing abilities and communication skills through *hearing aid fitting* (3.11), counselling, instruction, education, training and developing listening skills

Note 1 to entry: The term "habilitation" includes all rehabilitation processes with additional interventions to develop listening, speech and language skills for prelingually deafened individuals such as children which are outside the scope of this document.

3.15
maximum output
maximum sound pressure level at the output of a *hearing aid* (3.9) as adjusted by the *HAP* (3.13)

3.16
pre-setting of hearing aids
configuration and adjustment of a *hearing aid* (3.9) using a prescriptive rule and relevant audiological data

3.17
verification
provision of objective evidence that a given item fulfils specified requirements

Note 1 to entry: In the field of *hearing aid fitting* (3.11), the verification usually means evaluating physical, electroacoustic and psycho-acoustic aspects of a hearing aid fitting by presenting signals to *hearing aids* (3.9) in a hearing aid test box or a real-ear or by using functional gain measurement in accordance with ISO 8253-2.

[SOURCE: ISO/IEC Guide 99:2007, 2.44, modified - Examples removed, original Notes to entry replaced with Note 1 to entry.]

3.18
validation
verification (3.17), where the specified requirements are adequate for an intended use

Note 1 to entry: In the field of *hearing aid fitting* (3.11), the verification usually means a comprehensive evaluation of the user benefits of a hearing aid fitting using methods which include speech audiometry and subjective response questionnaires.

[SOURCE: ISO/IEC Guide 99:2007, 2.45, modified - Example removed, Note 1 to entry added.]

4 Service preconditions

4.1 General

For quality service provision, the following preconditions shall be fulfilled:

— educational requirements;

— facility requirements;

— equipment requirements;

— ethical requirements.

Further preconditions are given by local applicable laws and regulations.

4.2 Educational requirements

4.2.1 General

The competencies of persons delivering the service are essential to the quality of service and should be rooted in appropriate education from recognized educational institutions and organisations as well as relevant practical skills obtained in a structured process. Ongoing education is required as it is vital to maintaining the competencies, skill levels and knowledge needed for best practice.

In general, delegation of tasks to staff without the required education should not be permitted. More than one type of staff can perform certain tasks in accordance with their specific educational background following national or regional regulations. The overall responsibility of the service provision shall rest with a HAP with the education specified in 4.2.2.

In order to facilitate the acquisition of practical skills, practices may include trainees from educational programs in their staff. Services performed by trainees shall take place under the supervision of a qualified HAP who shall be present at the facilities and who remains responsible for all activities carried out by the trainee.

4.2.2 Requirements for hearing aid professionals

A minimum education level 5 according to the International Standard Classification of Education, ISCED, or equivalent is required in order to perform all stages of hearing aid fitting management. A level 6 education is recommended.

It is recommended that the educational program includes the following academic topics: basic mathematics and science including acoustics, anatomy and physiology, psychology and linguistics, audiology, hearing aid technology, hearing rehabilitation processes, hearing aid fitting.

The following practical skills should be obtained through training: client interaction, audiometric measurements, earmould management, hearing aid programming, fitting verification and validation, hearing aid modification and repair.

Suggestions for minimum competencies of the HAP and a suitable education program are given in Annexes A and B, respectively.

Any HAP shall have proven minimal competencies through testing in order to practice independently.

NOTE It is recognized that developing countries sometimes do not readily have access to this level of education.

4.2.3 Maintenence of competencies and skills of hearing aid professionals

Hearing aid professionals shall receive ongoing education to maintain the competencies and increase skill levels. Ten hours annually is the minimum, 20 hours or more is recommended.

Ongoing education can be acquired in multiple ways such as: in-class training, conferences, manufacturer's courses, e-learning, webinars and other recognized sources.

4.3 Facility requirements

4.3.1 General

Facilities for hearing aid provision should be of sufficient size to facilitate reception of clients, hearing assessment, hearing aid provision, and maintenance of hearing devices. The facilities shall have a size that can accommodate the clinician, the client and at least one accompanying person. Facilities shall be clean, safe and readily accessible for persons with disabilities. Facilities should also have access to running water and toilets. The practice should be clearly identifiable and provide access to contact via telephone, SMS, fax, website or email. Hours of operation should be publicly accessible.

Facilities for the cleaning and disinfection of equipment shall be available. Moreover, hand washing facilities and containers for the disposal of single use (and potentially contaminated) items should also be provided.

4.3.2 Room requirements

Any consultation area shall be sufficiently private so that any other persons within the facility are not able to overhear conversations taking place. In addition, an appropriate ventilation and temperature control sould be considered, since sound treated rooms can become warm and unpleasant.

Audiometric testing rooms/areas shall comply with maximum ambient noise levels in accordance with ISO 8253-1, and ISO 8253-3, to allow threshold levels to be measurable down to 20 dB HL for air conduction, and 30 dB HL for bone conduction. If it is desired to do sound field audiometry, the ambient noise levels shall be in accordance with ISO 8253-2 for measurable threshold levels down to 20 dB HL. Fitting areas also require a controlled acoustic environment where:

— the reverberation time should be less than 0,5 s at 500 Hz;

— the equivalent A-weighted sound pressure level of the ambient noise shall be less than 45 dB under usual operating conditions averaged over at least 30 s;

  The 30 s measurement period shall be representative of the steady-state ambient noise in the fitting area. If a longer measurement period leads to a different result, the averaging time shall be increased.

— no dominant pure-tone components are in the ambient noise;

— the minimum floor surface area is 10 m^2 and the minimum volume is 25 m^3.

An example of a fitting room is shown in Annex C.

4.4 Equipment requirements

4.4.1 General

In order to provide quality services, a range of equipment is required. The equipment cited below is considered the minimum requirement. All equipment shall be specific to the functions required and fit for purpose.

4.4.2 Audiometric equipment

For pure-tone audiometry, an audiometer shall be used for testing of air-conduction and bone-conduction thresholds using masking when required. The audiometer can be part of an integrated system with multiple functional modes. A pure-tone audiometer can also be used for measurement of the most comfortable loudness level (MCL) and uncomfortable loudness level (UCL).

The audiometer shall be a pure-tone audiometer of Type 1 or Type 2 as specified in IEC 60645-1:2017.

The performance of this equipment shall be checked and calibrated according to ISO 8253-1.

For speech audiometry, equipment fulfilling the requirements of IEC 60645-1 shall be available. Power amplifier and loudspeaker shall be available if sound field speech audiometry is performed. The performance of this equipment shall be checked and calibrated according to ISO 8253-3.

The maximum interval between objective periodical checks of the audiometric equipment shall not exceed 12 months. National or regional legislation can call for more frequent checks.

A tympanometer is recommended for impedance measurements to identify possible causes of conductive hearing loss and possible reasons for referral. The performance of this equipment shall be checked and calibrated according to IEC 60645-5.

4.4.3 Equipment for otoscopy and earmould impressions

For inspection of the ear-canal and tympanic membrane, an otoscope with ear specula of different sizes shall be available. Equipment for taking ear impressions shall also be available. For impression taking by moulding techniques the following shall be available: moulding syringes or moulding gun with suitable compounds for making earmould impressions; otoblock/cotton dam; hygiene products for hands and equipment. Ear impressions can also be taken by means of ear scanning systems.

4.4.4 Hearing aid programming equipment

A computer system with suitable hardware and software for hearing aid programming and storing of relevant client and fitting data shall be available.

4.4.5 Electroacoustic measurement equipment

Electroacoustic equipment for measuring hearing aid characteristics on an acoustic coupler or ear simulator (gain, output level, distortion, induction pick-up coil sensitivity, etc.) in accordance with IEC 60118-7 shall be available.

Equipment for in-situ measurement of real-ear acoustical characteristics of hearing aids fulfilling the requirements of IEC 61669 shall be available. The International Speech Test Signal (ISTS) as defined by IEC 60118-15 should be available for in-situ measurements.

A sound calibrator can be useful for in-practice calibration and checks of acoustic equipment.

It is recommended that the intervals between calibrations of electroacoustic measurement equipment do not exceed twelve months.

4.4.6 Maintenance tools

Tools and accessories required depend on the services offered. The following equipment is recommended for maintenance of hearing aid systems:

— tools for drilling and polishing;

— ultrasonic bath;

— set of screwdrivers, pliers and scalpel;

— scissors, forceps, disinfectant, sound tubes;

— picks and brushes;

— stethoscopic listening device;

— binocular magnifying glass or illuminated magnifying glass;

— vacuum pump, compressor or aerosol.

4.4.7 Demonstration samples

For demonstration of products, a selection of hearing aids, accessories and other assistive hearing devices should be available. Wireless connectivity devices such as wireless remote microphone systems (WRMS), TV-streamers, etc. should be part of the selection of accessories. An induction loop can also be useful for demonstration of telecoils.

4.5 Ethical requirements

4.5.1 General

The HAP shall always work with the goal of achieving the best possible solution for the client.

4.5.2 Professional competence

HAPs shall practice only within their scope of training, experience and competence. They should engage in the provision of hearing health care that represents the prevailing standard of practice and shall participate in a regular program of ongoing education.

Annex A gives a detailed suggestion for minimum competencies of the HAP.

4.5.3 Relationship with clients

In all dealings with clients, the HAP shall be respectful and keep all personal information gathered private and confidential.

The HAP shall treat clients with respect, honesty and not abuse or exploit the client psychologically, sexually, physically or financially.

4.5.4 Conflict of interest

The HAP is entitled to reasonable compensation for services to or on behalf of clients. The HAP shall not engage in practices and financial arrangements influencing decisions in the best interest of the clients. The HAP shall receive compensation only for services actually rendered to the client and not receive or pay a fee for making a referral. The HAP shall refrain from competition adverse arrangements that infringe the ethics of the profession. This includes collusion with medical practitioners, hearing aid manufacturers or other third-party health care professionals resulting in circumvention of normal competitive conditions.

When a HAP makes a written or oral public statement concerning a product of a company from which they receive compensation, or a company which holds a significant equity position in the practice or a company which they hold a significant equity position in, the HAP shall disclose the financial relationship with that company.

4.5.5 Relationship with medical and other health practitioners

Hearing aid professionals shall represent themselves and their credentials to the public in a truthful and honest fashion. A HAP should cooperate and communicate with other health care professionals in order to provide the best care possible to clients.

When a HAP recognises that communication and/or hearing problems can be caused by medical conditions that require medical treatment, they shall refer to an appropriate medical practitioner. Annex D gives guidance on indications that lead to a medical referral and how to interact with clients in these situations.

The HAP shall undertake to make available to the physician and other involved service providers all necessary and relevant documentation with consent of the client.

4.5.6 Relationship with colleagues

A HAP shall refrain from unjustifiable criticism of colleagues' judgement, training, knowledge or skills. A HAP shall not knowingly ignore professional misconduct or incompetence and shall report it to their superior, professional college or applicable authority.

4.5.7 Advertising

A HAP often advertises their services. The requirements related to such advertising are given in applicable national or regional directives and legislation.

5 General stages of HAFM

5.1 General

The stages of HAFM shall be performed by a hearing aid professional, to ensure the best possible outcome and adequate service in the interest of the client. These stages cover assessment of the client's needs and degree of hearing loss followed by the selection and fitting of suitable hearing aids, rehabilitation and short and long-term monitoring and support.

Hearing aid fitting shall consist of the delivery of the hearing aids, the fitting process and the related care. The efficacy of the hearing aid system depends on the type of device chosen, its fitting, the counselling and the follow-up.

Initially, the general process of HAFM shall be explained to the client, including the financial aspects. During the entire fitting process, decisions shall be made in a close dialogue with the client after counselling by the HAP (informed consent).

Annex E gives a comprehensive set of suggestions for how to communicate with the client in accordance with the principles of person centered care.

The HAP shall pay particular attention to clients with no previous experience in using hearing aids.

The general framework of HAFM consists of six stages, as depicted in Figure 1: client profile, counselling, hearing aid fitting, verification and validation, post-fitting counselling and follow-up. This general framework includes all the necessary activities for best practice HAFM. The stages are listed in non-chronological order. The client may pass through these stages in a different order, with an overlapping with other stages, or multiple times due to an iterative approach.

