

SVENSK STANDARD

SS-ISO 21388:2020

Akustik – Process för utprovning av hörapparater  
(ISO 21388:2020, IDT)

Acoustics – Hearing aid fitting management (HAFM)  
(ISO 21388:2020, IDT)



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Den internationella standarden ISO 21388:2020 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av ISO 21388:2020.

The International Standard ISO 21388:2020 has the status of a Swedish Standard. This document contains the official English version of ISO 21388:2020.

## LÄSANVISNINGAR FÖR STANDARDER

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Ett krav är ett uttryck i ett dokumentets innehåll som anger objektivet verifierbara kriterier som ska uppfyllas och från vilka ingen avvikelse tillåts om efterlevnad av dokumentet ska kunna åberopas. Krav uttrycks med hjälpverbet ska (eller ska inte för förbud).

### Rekommendation

En rekommendation är ett uttryck i ett dokumentets innehåll som anger en valmöjlighet eller ett tillvägagångssätt som bedöms vara särskilt lämpligt utan att nödvändigtvis nämna eller utesluta andra. Rekommendationer uttrycks med hjälpverbet bör (eller bör inte för avrådanden).

### Instruktion

Instruktioner anges i imperativ form och används för att ange hur något görs eller utförs. De kan underordnas en annan regel, såsom ett krav eller en rekommendation. De kan även användas självständigt, och är då att betrakta som krav.

### Förklaring

En förklaring är ett uttryck i ett dokumentets innehåll som förmedlar information. En förklaring kan uttrycka tillåtelse, möjlighet eller förmåga. Tillåtelse uttrycks med hjälpverbet får (eller motsatsen behöver inte). Möjlighet och förmåga uttrycks med hjälpverbet kan (eller motsatsen kan inte).

## READING INSTRUCTIONS FOR STANDARDS

These instructions cover the main principles for the use of provisions and external constraints in standardization deliverables.

### Requirement

A requirement is an expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled, and from which no deviation is permitted if conformance with the document is to be claimed. Requirements are expressed by the auxiliary shall (or shall not for prohibition).

### Recommendation

A recommendation is an expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable, without necessarily mentioning or excluding others. Recommendations are expressed by the auxiliary should (or should not for dissuasion).

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An instruction is expressed in the imperative mood and is used in order to convey an action to be performed. It can be subordinated to another provision, such as a requirement or a recommendation. It can also be used independently and is then to be regarded as a requirement.

### Statement

A statement is an expression, in the content of a document, that conveys information. A statement can express permission, possibility or capability. Permission is expressed by the auxiliary may (its opposite being need not). Possibility and capability are expressed by the auxiliary can (its opposite being cannot).

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## 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](http://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](http://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](http://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](http://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<sup>[22]</sup>. Hearing aids (HAs) are one of the most widely-used treatment options for people with a hearing loss<sup>[39][40]</sup>. 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<sup>[39][42][43]</sup>. Individually optimized outcome of HA use is supported by comprehensive HA fitting protocols<sup>[42]</sup> and the impact of “poor fit and comfort” can lead to non-compliance, HA return<sup>[43]</sup> 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<sup>[16][44]-[46]</sup> 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<sup>[17][18][23]-[32][34]-[37][47][48]</sup>, 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 Cultural Organization, 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.]