BS EN ISO 21388:2021

BSI Standards Publication

Acoustics — Hearing aid fitting management (HAFM)

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 21388:2021. It is identical to ISO 21388:2020. It supersedes BS EN 15927:2010, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EH/1/1, Hearing.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2021

ISBN 978 0 539 16567 8

ICS 11.020.10; 11.180.15; 17.140.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2020.

Amendments/corrigenda issued since publication

Date	Text affected
30 September 2021	This corrigendum renumbers BS ISO 21388:2020 as BS EN ISO 21388:2021. The supersession details in the national foreword have also been updated.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21388

July 2021

ICS 11.020.10; 11.180.15; 17.140.01

Supersedes EN 15927:2010

English Version

Acoustics - Hearing aid fitting management (HAFM) (ISO 21388:2020)

Acoustique - Gestion des appareils de correction auditive (ISO 21388:2020)

Akustik - Hörgeräteanpassungsmanagement (HAFM) (ISO 21388:2020)

This European Standard was approved by CEN on 11 July 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of ISO 21388:2020 has been prepared by Technical Committee ISO/TC 43 "Acoustics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21388:2021 by Technical Committee CEN/TC 211 "Acoustics" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2022, and conflicting national standards shall be withdrawn at the latest by January 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 15927:2010.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 21388:2020 has been approved by CEN as EN ISO 21388:2021 without any modification.

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.

INTERNATIONAL STANDARD **ISO 21388:2020**

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*