Akustika - Vodenje ustreznosti slušnih pripomočkov - 2. del: Tele-storitve kot del vodenje ustreznosti slušnih pripomočkov (tHAFM) (ISO/DIS 21388-2:2023)

Acoustics - Hearing Aid Fitting Management - Part 2: Tele-services as part of hearing aid fitting management (tHAFM) (ISO/DIS 21388-2:2023)

Akustik - Hörgeräteanpassungsmanagement - Teil 2: Teledienste als Teil des Hörgeräteanpassungsmanagements (tHAFM) (ISO/DIS 21388-2:2023)

Acoustique - Gestion de l'appareillage auditif - Partie 2: Téléservices dans le cadre de la gestion des ajustements auditifs (tHAFM) (ISO/DIS 21388-2:2023)

Ta slovenski standard je istoveten z: **prEN ISO 21388-2**

ICS:

11.020.10	Zdravstvene storitve na splošno	Health care services in general
11.180.15	Pripomočki za gluhe osebe in osebe z okvaro sluha	Aids for deaf and hearing impaired people
17.140.01	Akustična merjenja in blaženje hrupa na splošno	Acoustic measurements and noise abatement in general

oSIST prEN ISO 21388-2:2023 **en,fr,de**

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Part 2:
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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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*.

A list of all parts in the ISO 21388 series can be found on the ISO website.

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 importance of tele-service delivery and accessibility in hearing aid fitting management (HAFM) has highlighted.[6-11] A tele-service as part of HAFM (tHAFM) is an alternative method delivering essential intervention services through telecommunication. The main purpose of this document is to provide a general framework for tHAFM stages and to achieve the best hearing rehabilitation outcome equivalent to traditional face-to-face services, which can be accomplished through adequate education and service environments, skills of professional and a systematic approach to tHAFM.

This document thus covers important preconditions such as professional liability and training, service facilities and systems that are required to ensure proper tele-services. The general framework of HAFM with tele-service labels defines services which shall be provided in the facilities of the HAP and consists of client candidacy assessment, general assessment, pre and post counselling, fine-tuning, and follow-up.

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DRAFT INTERNATIONAL STANDARD ISO/DIS 21388-2:2023(E)

Acoustics — Hearing Aid Fitting Management —

Part 2:
Tele-services as part of hearing aid fitting management (tHAFM)

1 Scope

This document is a supplement to ISO 21388 which applies to hearing aid fitting management (HAFM) services offered by hearing aid professionals (HAP). It focusses on tele-services which may substitute, or complement services defined in ISO 21388, and it defines services which shall be provided in the facilities of the HAP. Moreover, this document specifies important preconditions such as education, facilities and systems that are required to ensure proper tele-services. If not other stated all definitions and requirements of ISO 21388 also apply for this standard without further notice. Furthermore, it is tried to keep the structure of ISO 21388 to make it easier to use both standards together. 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.

Assisted tele-services provided by non-hearing aid professionals, self-fitting, and other non-hearing care related services are also outside the scope of this document.

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

ISO 13131:2021, *Health informatics — Telehealth services — Quality planning guidelines*

ISO 21388, *Acoustics — Hearing aid fitting management (HAFM)*

IEC 60118-15, *Electroacoustics — Hearing aids — Part 15: Methods for characterising signal processing in hearing aids with a speech-like signal*

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

ITU-T F.780.2, *Accessibility of telehealth services*

WHO-ITU global standard for accessibility of telehealth services. World Health Organization, 2022.

3 Terms and definitions

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

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

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

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

ISO/DIS 21388-2:2023(E)

3.1
tele-service
health-service provided remotely by means of a telecommunication link

3.2
hearing aid professional
HAP
person who is appropriately trained and has proven competency in professionally assessing hearing, selecting, fitting and delivering hearing aid systems and rehabilitation services to persons with hearing loss

[SOURCE: ISO 21388:2020,3.13]

3.3
client
person with hearing loss being serviced by a *HAP* ([3.3](#))

[SOURCE: ISO 21388:2020,3.2]

3.4
informal care giver
person assisting a *client* ([3.2](#)) in tasks not directly related to hearing aids

Note 1 to entry: In a remote environment the client maybe needs support for tele-services, e.g., setting up an internet connection. However, it is not meant that an informal car giver replaces any tasks usually done by the HAP, e.g., otoscopy, taking an ear impression, placing a probe microphone, programming hearing aids, performing audiological tests, etc.

3.5
synchronous tele-service
real-time interaction
tele-service ([3.7](#)) where *HAP* ([3.3](#)) and *client* ([3.2](#)) are participating at the same time

3.6
ecologic momentary tele-service
tele-service ([3.7](#)) where the evaluation of or the fine tuning for a specific situation is performed while the *client* ([3.2](#)) is present in this specific situation

3.7
traditional service
services provided in the facilities of and by the *HAP* ([3.2](#))

4   Service preconditions

4.1   General

For quality service provision, in addition to the preconditions of ISO 21388, the following preconditions shall be fulfilled, if tele-services are used.

Further preconditions are given by local applicable laws and regulations.

When delivering tele-services HAPs should note the risks of safe and effective hearing care associated with:

— privacy and security of clients' sensitive information;

— technical failure;

— under-developed "soft skills" in communicating with clients during a real time teleaudiology service;

— lack of skills or preparation to navigate technical requirements.