



International
Standard

ISO 21388-2

**Acoustics — Hearing aid fitting
management —**

Part 2:

**Tele-services as part of hearing aid
fitting management (tHAFM)**

Acoustique — Processus d'adaptation des aides auditives —

*Partie 2: Télé-services dans le cadre du processus d'adaptation
des aides auditives*

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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 document 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).

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This document was prepared by Technical Committee ISO/TC 43, *Acoustics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 211, *Acoustics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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 been highlighted^{[1][2][3][4][5][6]}. 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 should 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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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 can substitute, or complement services defined in ISO 21388, and it defines services which is 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 document 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, *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*

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/>

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 disorder being serviced by a *HAP* (3.2)

[SOURCE: ISO 21388:2020, 3.2]

3.4
informal assistant

person assisting a *client* (3.3) but not in charge of the hearing aid fitting and not necessarily trained for this assistance

Note 1 to entry: In a remote environment the client may need support for tele-services, e.g. setting up an internet connection. However, it is not meant that an informal assistant 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

tele-service (3.1) where *HAP* (3.2) and *client* (3.3) are participating at the same time

3.6
ecologic momentary tele-service

tele-service (3.1) where the evaluation or the fine-tuning of the hearing aid configuration for a specific situation is performed while the *client* (3.3) is present in this specific situation

3.7
traditional service

services provided by the *HAP* (3.2) while the *client* (3.3) and the *HAP* (3.2) are simultaneously present in the facilities of 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;
- insufficient skills in communicating with clients during tele - service;
- lack of skills or preparation to navigate technical requirements.

HAPs should be aware of the risk of the tele-services from the client's perspective:

- potentials of depersonalised care, contributing to isolation and loneliness;
- inequitable access for those who are less tech savvy or less resourceful;

- challenges of navigating complex information and technical requirements;
- security of their sensitive data.

Digital health technologies increase opportunities for others to intercept information so the HAP shall take all reasonable steps to ensure personal health information is transmitted, managed, and stored in a secure and confidential manner and shall

- use a stable and reliable internet connection between client and HAP,
- comply with applicable privacy principles, privacy acts and regulations that govern electronic storage and transmission of client information,
- implement security measures for protecting clients' personal health information from unauthorised access through devices used for tele-services or online or cloud based by using measures to ensure confidentiality such as, password protection, data encryption and/or anonymising patient information, a secure network, and two factor authentication,
- understand the security features of the tele-services platform and data networks including which security features are default and which must be managed or activated by the HAP or client,
- avoid public Wi-Fi or internet hotspots to connect to a session or transmit client information unless encryption is activated, e.g. virtual private network (VPN), and
- use computers and other equipment that are dedicated to their professional work. If more than one user accesses a device, client related information shall be secured and password-protected.

HAP and client's environment shall be secure. The HAP shall

- request the client to ensure that client's environment is private,
- identify anyone who may be present with the client and determine, in consultation with the client, their roles in the session,
- ensure that others will not be able to observe audio or video of the session without consent from the client, and
- ensure that protected health information and other confidential data is only backed up to or stored on secure data storage locations.

4.2 Educational requirements for HAPs providing tele-services as part of hearing aid fitting management (HAFM)

In order to provide tele-services as part of HAFM, the HAP shall be trained in the essential aspects of tele-services at least covering the below topics:

- understanding the terminology;
- ICT (information and communications technology) for tele-services in HAFM including transmission channels, properties and communication-quality considerations;
- preparing tele-services in HAFM including client assessment of candidacy and on boarding and script and check lists;
- understanding the limitations and opportunities of tele-services in HAFM;
- documentation including identification in the fitting platform or CRM (customer relationship management)-system and significant parameters of the remote fine-tuning session.

4.3 Facility requirements (for tele-services)

4.3.1 General

The facility should be designed for effective tele-services and shall conform to ISO 13131.

Quiet and calm rooms to secure privacy also for tele-services are necessary. The background noise should not interfere with the tele-communication. Adequate room set up (at both ends) includes acceptable physical space and conditions to conduct counselling (e.g. good lighting, little or no background noise, distance for best use of camera), and ensures privacy and comfort (physical and emotional) of the client.

Stable and fast enough internet connection for functional tele-services is required.

4.3.2 Guidelines for client facilities

Consultations using tele-services take place in accommodation that is appropriate for the client to effectively participate in healthcare.

The client ensures the following:

- adequate physical space is available to conduct consultations;
- an appropriate level of comfort and privacy is available for the client and an informal assistant if required;
- equipment can be used effectively to transmit and receive an appropriate quality of information including audio or video information;
- equipment can be used in a safe manner.

Especially for synchronous tele-services special attention should be given to:

- internet connection quality;
- charging level of smartphone or other interphase smart device and the hearing instruments;
- noise sources and noise levels within the client's fitting environment;
- proximity to acoustically reflecting surfaces or openness of the environment;
- client's comfort and privacy;
- options for support by client's significant others (spouse, friends, children, etc.).

If ecologic momentary tele-services shall be applied, the HAP shall inform the client about limitations and potential risks (e.g. violated privacy) and the client's consent for ecologic momentary tele-services shall be obtained beforehand.

If quality issues that do not allow quality tele-services are encountered, the HAP shall stop the tele-service.

4.4 Equipment requirements

4.4.1 General

Tele-services depend on information and communications technologies to deliver healthcare and transmit health information over both long and short distances. Establishing adequate equipment including video equipment, communication systems with a high-speed internet connection, test equipment, and software programs/applications are critical.

Equipment and clinical tools are safe and sufficient to support tHAFM services (e.g. counselling and fine-tuning), and function properly at the time of clinical encounters. This includes having available additional types of technologies or peripheral devices (e.g. fitting software etc.) that may be necessary to provide tele-services.