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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

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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.

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 maybe needs 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.

Since these technologies are part of the healthcare process, quality objectives should be established for information and communication technology service support, service delivery, infrastructure management, deployment management, operations management, and technical support.

General-purpose IT infrastructure including testing equipment, computer, video conference unit, desktop share software, ongoing real time image, audio controller and communication can be used to support tele-services. In addition, electronic data transmission system, high quality and speedy internet connection at both ends to deliver audio and video communication, and data security are needed.

Tele-service compatible hearing aid technology (e.g. hearing aids via remote programming or app services for client participation) is beneficial for remote support. Telephone based service can be used as a back-up in instances of poor internet connection. Telephone communication does allow a HAP to provide remote support to clients to help address and troubleshoot difficulties experienced with their devices. People with severe hearing loss often experience difficulty communicating over the telephone, and as such the broad applications of telephone-based services are questionable.

Advances in hearing aid and mobile phone technology, smart device applications allow remote adjustments and provide infrastructure for tele-service appointments. Different manufacturers offer different tele-services like asynchronous, or synchronous support, text chat features, and video communication.

With the consent of the clients, HAPs may be able to access client data-logging information and can inform them on the potential need for troubleshooting. The advantages documented include readily available appointments to facilitate learning and increase consistency of device use; flexible appointments to help fit within family life; and opportunity for multiple family members to be involved, a valuable benefit given the importance of family-centred care.

The equipment shall conform to ISO 13131.

4.4.2 Guidelines for safety and quality

The relationship between the client, HAP, and any tele-service platform provider should be defined in a service level agreement that:

— includes instructions for use and information on the intended use of the device and tele-services;

— includes the supporting clinical evidence;

— ensures the information provided to the client is understandable by the client and the informal assistant;

— provides a system for post-market surveillance to detect deficiencies that occur after deployment of the tele-service including equipment or devices used by the client;

— enables the client to communicate problems with a service, equipment, or device to the HAP.

4.4.3 Guidelines for service support

The tele-service platform provider ensures that procedures are in place to maintain tele-service continuity and dependability using the following:

— incident management to manage changes in services;

— problem management to identify and resolve issues whose cause is unknown;

— change management to manage necessary alterations to services;

— release management for the introduction of new services.

When a problem occurs with the equipment that is necessary for the delivery of tele-services, procedures should specify how problems can be diagnosed, communicated, and resolved. Tele-service platform provider should ensure that measures are put in place to mitigate the impact of failures of information and communications technology due to events beyond their control.

4.4.4 Guidelines for service delivery

The HAP and tele-service platform provider ensure that procedures are in place for the following:

— service level agreements specifying the levels of service required to support the agreed continuity of care;

— financial arrangements that account for the costs and charges to users of tele-services;

— capacity management ensures that IT infrastructure resources are in place to effectively meet planned demand for tele-services;

— availability management to ensure systems are dependable and available for use in accordance with the service level agreements provided to users of tele-services;

— service continuity management to provide recovery plans for tele-services when there is a significant failure.

For a device, the service level agreement in the purchase contract is subject to medical device standards when or if the device is intended by the manufacturer to be used, alone or in combination, for tele-service activities.

Service level agreements included the following:

— the desired characteristics, objectives and required procedures to ensure the quality objectives of tele-service;

— quality characteristics for the service, including aspects such as privacy;

— responsibilities and liability;

— documentation and auditing processes;

— financial management arrangements.

When tele-service platform providers cannot reach service level agreements with other providers such as internet or application service providers, they should rely on the information that has been provided by the hearing aid manufacturer or service provider for determining the quality of the device or service used in the tele-service and undertake a risk assessment of the suitability of the device or service for application in tele-services.

4.4.5 Guidelines for infrastructure management

The tele-service platform provider ensures that the infrastructure used for tele-services:

— is based on an accountable requirements analysis and planning process covering design, deployment, operations and technical support;

— supports interoperability using appropriate standards with other tele-services;

— is usable and fit for purpose;

— communicates dependably over the available telecommunication services;

— is financially efficient of the whole of the infrastructure life cycle.

Infrastructure can include equipment, software, telecommunications, and computer networks.

4.4.6 Guidelines for deployment management

The tele-service platform provider ensures that procedures are in place for the following:

— design, build, test and roll-out of equipment and devices for tele-services using an appropriate project management methodology;

— confirmation that the equipment or software is usable for tele-services;

— confirmation that the equipment or software is safe to operate;

— installation of equipment and devices for tele-services according to the guidelines of the manufacturer;

— repair or replacement of defective equipment and devices;

— removal of the equipment and devices.

4.4.7 Guidelines for operations management

The tele-service platform provider and HAP ensure that ICT operations management can provide day to day technical supervision of the ICT infrastructure used for tele-services including the following:

— timely support for all users;

— backup and restore services;

— network monitoring and management;

— system monitoring and management;

— database monitoring and management;

— storage monitoring and management;

— a stable, secure ICT infrastructure;

— management of technical diversity.

4.4.8 Guidelines for technical support

The tele-service platform provider provides technical support for tele-services that includes the following:

— research and evaluation;

— market intelligence gathering;

— proof of concept and pilot engineering;

— provision of specialist technical advice;

— documentation management.

4.4.9 Guidelines for device management

The hearing aid manufacturer, tele-service platform provider and HAP ensure that the devices used for tele-services:

— are usable and fit for purpose;

— are supported by the relevant information, including the clinical evidence for the effectiveness of the device;

— support interoperability using appropriate standards with other tele-services;

— communicate dependably over the available telecommunications services;

— are accompanied by service level agreements that can support the agreed continuity of care.

— Devices can consist of hardware, software, and telecommunication elements.

4.5 Ethical requirements

The ethical requirements of tHAFM in accordance with ISO 21388 shall be applied. In particular, the protection of personal and health data as well as the client's consent shall be respected.

The client has easy access to plain language information about tele-services, plus the other relevant options for providing care. The clients shall be informed which tele-services will be performed and what is expected of them. Clients shall give informed consent to the use of tele (verbally or in writing), including involvement of other HAPs, recording the session, the structure and timing of services, record keeping, scheduling, privacy and security, potential risks, confidentiality, mandatory reporting, billing, and any information specific to the nature of tele-services. HAPs shall have a mechanism in place to ensure that clients are aware of their rights and responsibilities with respect to accessing tele-services and/or their personal health records including the process for communicating complaints and grievances.

HAPs shall be aware of and comply with all applicable professional regulations and any guiding scope of practice policies. HAPs shall be aware of and comply with laws and regulations and shall integrate applicable guidelines, and standards, privileging, accrediting, and regulatory requirements for licensing, certification, professional liability, and ongoing professional development or training for use of IT for delivering provisional services and devices.

5 Tele-services as part of the general stages of HAFM

5.1 General

Tele-services as part of the stages of HAFM shall be performed by a HAP, to ensure the best possible outcome and adequate service in the interest of the client independent if these services are provided in the facilities and in physical presence of a HAP or remotely via tele-services.

Quality and effectiveness of the tele-services shall not be significantly reduced as compared to traditional services.

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. When a part of a stage can be done as tele-service, this is indicated with the label “tele-service”.

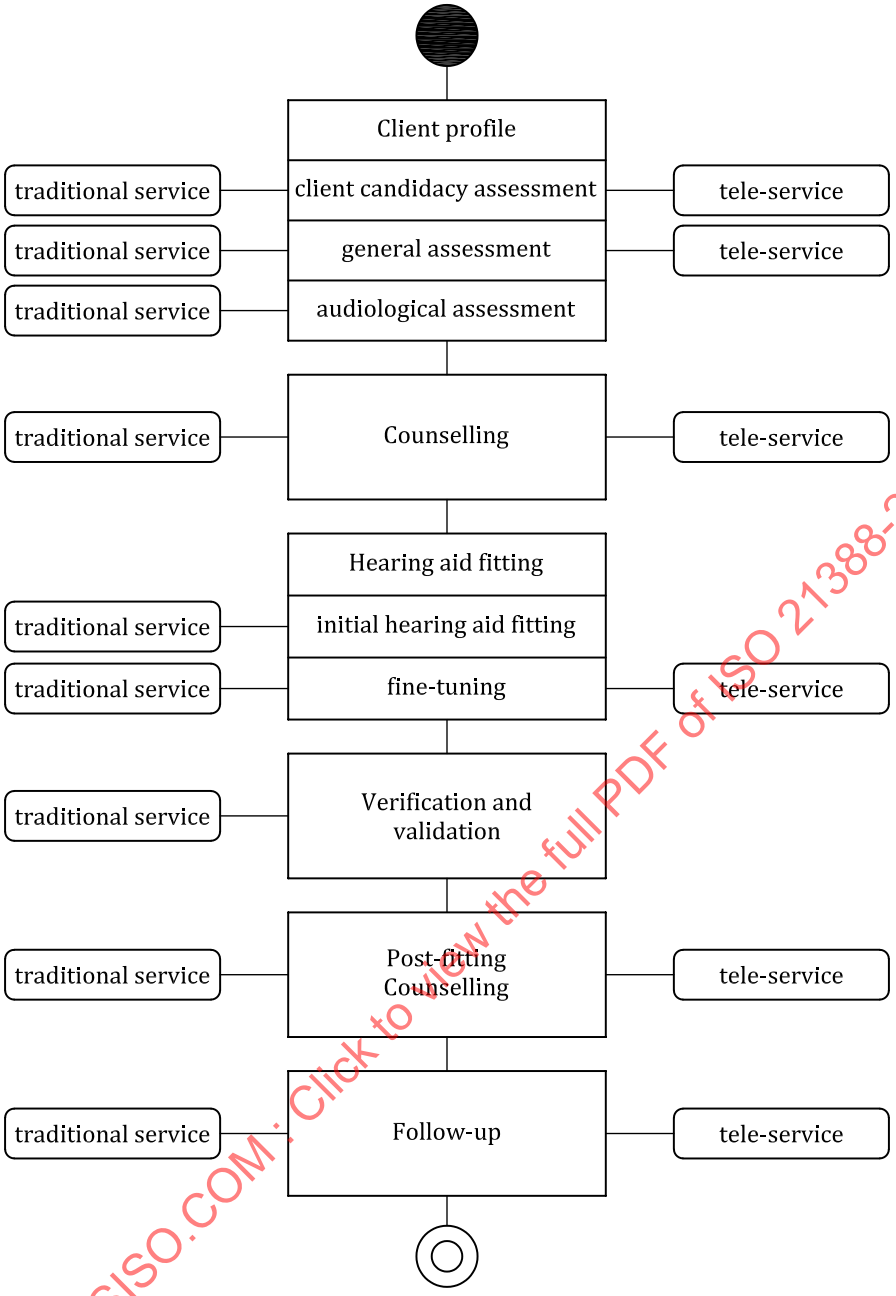

Figure 1 — General stage of HAFM with tele-service labels

5.2 Client candidacy and profile

The client candidacy for tele-services shall be assessed. Tele-services may not be appropriate for every client or for each client every time. The decision to use tele-services should be made on a case-by-case basis in consultation with the client. For the candidacy, the client's functionality with or without assistance of an informal assistant, like tech-savviness, dexterity, visual, cognitive, or other capabilities need to be taken into account.

Special care shall be taken to document client's skills to:

— operate and hold the connecting smartphone;

— properly mount the hearing instruments;

— accept and process instructions;

— understand and answer questions;

— assess the effect and quality of fitting actions provided by tele-services.

It is strongly recommended that the tele-services, the software, and the platform used for the tele-services are inclusive and accessible for the majority of candidate clients, and complied with ITU-T F.780.2, accessibility of telehealth services and WHO-ITU global standard for accessibility of telehealth services.

The client needs to be informed on the potential and limits of tele-services to avoid over-expectations or misunderstandings.

When the candidacy of a client is positive, the client does need to give an informed consent to tele-services and needs to get the opportunity for traditional services, HAFM as described in ISO 21388.

The general assessment (ISO 21388:2020, 5.2.2) may be done as tele-service, e.g. using video chat.

The audiological assessment (ISO 21388:2020, 5.2.3) shall be done as traditional services.

5.3 Counselling

The counselling (ISO 21388:2020, 5.3) may be done as tele-service, for clients that have the candidacy requirements and have given consent for counselling as tele-services at the condition that the HAP can provide quality and effective counselling. Counselling as tele-services shall follow set of suggestions for counselling topics with the client in ISO 21388.

5.4 Hearing aid fitting

The initial fitting shall be done in traditional service. Further adjustments (fine-tuning) of the hearing aids may also be performed by the HAP as tele-service, for clients that have the candidacy requirements and have given consent, at the condition that the HAP can provide quality, safe and effective fine-tuning.

If the intended results are not sufficient, the HAP shall consider planning the next fine-tuning session as traditional service.

5.5 Verification and validation

The verification and validation (ISO 21388:2020, 5.5) as listed below, shall be done as traditional service:

— real-ear measurements in accordance with IEC 61669;

— percentile analysis as defined by IEC 60118-15;

— functional gain (difference between unaided and aided hearing threshold) evaluation in sound field in accordance with ISO 8253-2;

— the hearing aid compression and maximum output;

— client's real-ear-to-coupler difference measurements;

— hearing aid adjustments by using recordings of typical real-life sounds;

— speech audiometry in a sound field without and/or with noise, aided compared to unaided;

— localisation performance using loudspeaker arrays.

5.6 Post-fitting counselling

The post-fitting counselling (ISO 21388:2020, 5.3) may be done as tele-service for clients that have the candidacy requirements and have given consent, on the condition that the HAP can provide quality and effective counselling. Tele counselling shall follow the set of suggestions for counselling topics with the client in ISO 21388.