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Services offered by hearing aid professionals

Services offerts par les audioprothésistes

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Services offered by hearing aid professionals

Services offerts par les audioprothésistes

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 380.

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Foreword

This document (prEN 15927:2009) has been prepared by Technical Committee CEN/TC 380 “Project Committee - Hearing aid specialist services”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

Introduction

The standard provides a set of minimum requirements for the essential elements of the service provision. Furthermore, recommendations for other aspects of good practice are provided.

Emphasis is placed on defining requirements for the elements of the service provision where the quality of the service offered is not readily assessed by the average client.

Certain aspects of the service delivery by hearing aid professionals are likely to be covered by other already existing standards. These may be other EU standards in their national implementation or local standards that implement certain national requirements. Examples of such aspects are: Business certificates, occupational safety and hygiene requirements, confidentiality and data protection.

The quality of the service delivered by hearing aid professionals is also influenced by how the service delivery is managed in terms of staff behaviour and motivation, design and layout of facilities, choice of suppliers and products. Such management and availability play an important role, but falls outside the scope of this standard.

1 Scope

This standard applies to the services offered by hearing aid professionals in their efforts to provide benefit for their clients.

The standard specifies the process of hearing aid provision from the first client contact to the long term follow-up. The standard also defines requirements for education, facilities, equipment and code of conduct. A quality management system with the over-all objective of securing client satisfaction and covering the elements of the service is also an essential part of the requirements.

The standard centres on the services offered to the majority of clients with hearing impairment. Certain groups of hearing impaired such as children, persons with other handicaps or persons with cochlear implants may require services beyond what is covered in this standard.

2 Normative references

The following referenced documents are indispensable for the application 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.

EN 60118-4, *Electroacoustics – Hearing aids – Part 4 : Induction loop systems for hearing aid purposes - Magnetic field strength*.

EN 60118-7, *Electroacoustics – Hearing aids – Part 7 : Measurement of performance characteristics of hearing aids for production, supply and delivery quality assurance purposes*.

EN 60645-1, *Electroacoustics – Audiometric equipment – Part 1 : Pure-tone audiometers*.

EN 60645-2, *Audiometers – Part 2 : Equipment for speech audiometry*.

EN 61669, *Electroacoustics – Equipment for the measurement of real-ear acoustical characteristics of hearing aids*.

EN 61672-1, *Electroacoustics – Sound level meters – Part 1 : Specifications*.

EN ISO 389-1, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 1 : Reference equivalent threshold sound pressure levels for pure-tones and supra-aural earphones*.

EN ISO 389-2, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 2 : Reference equivalent threshold sound pressure levels for pure-tones and insert earphones*.

EN ISO 389-3, *Acoustics – Reference zero for the calibration of audiometric equipment – Part 3 : Reference equivalent threshold force levels for pure-tones and bone vibrators*.

EN ISO 8253-1, *Acoustics – Audiometric test methods – Part 1 : Basic pure-tone air and bone conduction threshold audiometry*.

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

EN ISO 8253-3, *Acoustics – Audiometric test methods – Part 3 : Speech audiometry*.

EN ISO 9000. *Quality management systems – Fundamentals and vocabulary*.

EN ISO 9001, *Quality management systems – Requirements*.

EN ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*.

ISO 12124, *Acoustics – Procedures for the measurement of real-ear acoustical characteristics of hearing aids*.

ISO 16832, *Acoustics – Loudness scaling by means of categories*.

3 Terms and definitions

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

3.1
hearing aid professional
an audiologically competent person who professionally assesses hearing, selects, fits and delivers hearing systems and rehabilitation services to persons with hearing loss

3.2
hearing impaired
a person with hearing loss in one or both ears

3.3
client
a person with a hearing impairment being serviced by a hearing aid professional

3.4
hearing aid
a device designed to amplify and process sounds in order to compensate for a hearing loss based on electro-acoustic or electro-magnetic systems, placed outside or inside the ear

3.5
ear-mould
an individually customised or selected mechanical-acoustical coupling between a hearing aid and the ear canal

3.6
hearing system
an integral and customised device consisting of a hearing aid, ear-mould and related components such as a remote control or interfaces to other information or communication systems

3.7
hearing profile
a comprehensive account for a hearing impaired client's auditory problems, social situation, activity limitations, needs and expectations

3.8
fitting
a systematic procedure for adapting a hearing system to compensate for hearing loss

3.9
pre-setting
the adjustment of a hearing aid using a prescriptive rule and relevant audiological data

3.10
fine-tuning
the adjustment of the hearing system to best match the needs and preferences of the hearing impaired

3.11
auditory training
a set of procedures, exercises and tests used to improve a hearing impaired person's auditory performance

3.12
fitting system
a set of devices typically comprising a PC, fitting software and a programming interface used to adjust hearing aids

3.13
practice unit
a physical location where services are delivered by a hearing aid professional

3.14
rehabilitation
a systematic process for improving hearing abilities through education, training and instruction after hearing system fitting

4 Service preconditions

In order to provide a high quality service, certain preconditions and applicable national laws and regulations shall be fulfilled. These essential preconditions fall in four categories :

1) educational requirements specifying the competencies that shall be required to perform the services ;
2) facility requirements specifying how the appropriate environment shall be for the proper delivery of the services ;
3) equipment requirements specifying what the necessary equipment for performing the services shall be ;
4) ethical recommendations specifying what the ethical framework and code of conduct should be.

4.1 Educational requirements

This section specifies the competencies required for performing the hearing aid provision processes that are described in chapter 6 of the service specifications.

The competencies of the persons delivering the service are very important for the quality of the service and must be rooted in proper education from recognized educational institutions as well as relevant practical skills obtained in a structured process.

In general delegation of tasks to staff without the required education shall not be allowed. Some national regulations may allow for more than one type of staff to be allowed to perform certain tasks in accordance with their specific educational background. The overall responsibility of the service provision must rest with a person having the educational background specified in the following section 4.1.1.

In order to facilitate the acquisition of practical skills practice units may include trainees from educational programs in their staff. Services performed by trainees shall take place under the close supervision of the hearing aid professional that remains responsible for the activities.

4.1.1 Requirements for Hearing Aid Professionals

A robust foundation of knowledge and proficiencies in audiology and acoustics is a vital necessity for providing hearing and communication rehabilitation which meets the clients needs and expectations and the current standards of technological and medical progress.

The hearing aid professionals should actively seek information and training for state-of-the-art hearing and communication systems and their proper application.

In order to be in compliance with this standard the hearing aid professional shall hold qualifications recognized by applicable national laws and regulations concerning hearing aid services. The qualifications should correspond to point (d) of article 11 in Directive 2005/36/EC. However, as a minimum the qualifications shall correspond to a degree of Article 11 point (c) of this directive.

If no national regulations exist a degree equivalent to EQF-level-5 (EU 2008/C111/01) should be required. If national regulations are changed to require an EQF-level-5 education, the requirement shall be valid only from date of publication.

The skills and competencies for a sufficient education are outlined in Annex A.

4.1.2 Continued education

In order to continuously ensure high quality service provision the hearing aid professional shall keep current with the developments in the field of audiology, hearing aid technology, methods and procedures as well as related products. Such additional education can be achieved in several ways such as short courses, workshops, training seminars and conferences.

A minimum of 20 hours per year of a hearing aid professional's working time shall be devoted to continuing education.

4.2 Facility Requirements

The service units where hearing aid professionals deliver their services may vary considerably with regard to size, placement and surroundings in accordance with national preferences and legislation. Regardless of such differences the facilities of the practice unit shall meet standards that ensure proper performance of the services. In keeping with the service process descriptions in chapter 6 the following service areas shall be available :

— reception area ;

— counselling area ;

— audiometry area ;

— fitting area ;

— maintenance area.

The service provider shall ensure that the service is fully accessible to the clients, eg :

— it shall be easy to contact the service provider by telephone, telefax and/ or e-mail ;

— the access to the practice unit shall be clearly signed ;

— public information about contact and opening hours shall be given.

The facilities should be adequately designed for persons with hearing disabilities. This entails that the rooms should have low reverberation time and good lighting facilitating lip reading.

4.2.1 Reception

When entering the practice unit a reception desk should be readily available. At the reception clients can identify themselves to the personnel and be advised about the service options. Often the reception is naturally coinciding with the desk where sales of consumables and accessories take place. The desk should be equipped with an induction loop system. A waiting area should be naturally connected with the reception area and separated from the other service areas.

4.2.2 Counselling Area

A secluded area for counselling of clients shall be available. It shall be separated from the reception/waiting area in such a way that waiting clients cannot overhear conversations between the hearing professional and the client.

4.2.3 Audiometry and Fitting areas

Audiometric measurements can only reliably be performed in an area with the correct acoustic properties in terms of reverberation time and ambient noise level. Hearing threshold levels using headphones shall be measurable down to 20 dB HL which means that maximum ambient sound levels shall fulfil the requirements in EN ISO 8253-1. This requirement can be fulfilled by a sound insulating cabin for pure tone audiometric measurements.

Hearing aid fitting also requires a controlled acoustic environment although the specifications are less demanding in terms of ambient noise. The fitting area should fulfil the following requirements :

— a minimum surface area of 7 m^2 and a minimum volume of 15 m^3 ;

— reverberation time should be less than 0.5 s at 500 Hz ;

— an equivalent A-weighted ambient sound pressure level of less than 35 dB ;

— no dominant pure-tone components in the background noise.

The fitting area may also be used for pure-tone audiometry if the requirements on ambient noise levels are met.

For sound field speech audiometry the ambient sound pressure levels in the test room shall not mask the speech signals. A quasi-free sound field as specified in EN ISO 8253-2 is recommended.

A practice unit can have more than one audiometry and fitting areas.

NOTE Documents with detailed advice on calibration of sound field systems in a fitting area are available from the HIMSA website, www.himsa.com.

4.2.4 Maintenance area

The maintenance area is intended for service activities on hearing aids and other devices. It should be separated from the other areas. It should be ensured that activities in the maintenance area do not disturb (noise, fumes etc) the activities in the audiometry and fitting areas.

4.3 Equipment Requirements

In order to provide high quality services different types of equipment are needed for proper performance of the service processes and these are characterised in the subsequent sections.

The equipment listed below shall be available as minimum requirement in order to provide the proper services.

Means for documentation of measurement activity shall be available. Such means can be either paper based or computerized electronic records with print-out facilities.

4.3.1 Audiometric Equipment

For pure-tone audiometry an audiometer shall be used for testing for of air-conduction as well as bone-conduction using masking when applicable. The audiometer should be capable of measuring with headphones as well as insert phones. The audiometer can be part of an integrated system with multiple functional modes.

The audiometer shall be a pure-tone audiometer type 1 or 2 fulfilling the requirements of EN 60645-1. The performance of this equipment shall be checked and calibrated according to EN ISO 8253-1 and relevant parts of EN ISO 389.

For speech audiometry equipment fulfilling the requirements of EN 60645-2 shall be available including power amplifier and loudspeaker. The performance of this equipment shall be checked and calibrated according to EN ISO 8253-3.

The maximum interval between objective periodical checks of the audiometric equipment shall not exceed 12 months. If national legislation calls for more frequent, safety related checks these shall be applied.

4.3.2 Equipment for Otoscopy and ear-mould impressions

For examination of the ear-canal and tympanic membrane otoscopic equipment shall be available. Equipment for taking ear-mould impression shall also be available :

— otoscope with ear specula of different sizes ;

— moulding syringes or moulding gun with suitable compounds for making ear-mould impressions ;

— eardrum protectors ;

— hygiene products for hands and equipment.

4.3.3 Hearing Aid programming equipment

A computer system with suitable hardware and software for hearing aid programming and storing of relevant client and fitting data shall be available.

4.3.4 Electro-acoustic measurement equipment

The following equipment should be available :

— equipment for the measurement of real-ear acoustical characteristics of hearing aids fulfilling the requirements according to EN 61669 ;

— electro-acoustic equipment for measuring hearing aid characteristics on acoustic coupler or ear simulator (gain, output level, distortion, induction pick-up coil sensitivity etc.) in accordance EN 60118-7 ;

— the maximum interval between calibrations of such electro-acoustic equipment should not exceed 12 months ;

— a class 1 or 2 sound level meter according to EN 61672-1 should also be available.