SLOVENSKI STANDARD
SIST EN 15927:2010

01-oktober-2010

Storitve ponudnikov slušnih pripomočkov

Services offered by hearing aid professionals

Dienstleistungen in der Hörakustik

Services offerts par les audioprothésistes

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Ta slovenski standard je istoveten z: **EN 15927:2010**

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ICS:

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15927

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ICS 11.180.15

English Version

Services offered by hearing aid professionals

Services offerts par les audioprothésistes

Dienstleistungen in der Hörakustik

This European Standard was approved by CEN on 12 June 2010.

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Foreword

This document (EN 15927:2010) has been prepared by Technical Committee CEN/TC 380 “Project Committee - Hearing aid specialist services”, the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by February 2011, and conflicting national standards shall be withdrawn at the latest by February 2011.

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

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Introduction

This European 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 European 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. The quality of the service delivered by hearing aid professionals relies on the personnel, their competencies and their motivation. Management plays an essential role. Quality requires the initial and continuing training of all the personnel, and an ongoing exchange of multidisciplinary expertise.

Such management and availability play an important role, but falls outside the scope of this European Standard.

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1 Scope

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

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

This European 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 disabilities or persons with implantable devices may require services beyond what is covered in this European 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*

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

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EN 60645-1, *Electroacoustics — Audiological equipment — Part 1: Pure-tone audiometers*

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

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EN 60645-5, *Electroacoustics — Audiometric equipment — Part 5: Instruments for the measurement of aural acoustic impedance/admittance*

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 (ISO 389-1:1998)*

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 (ISO 389-2:1994)*

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 (ISO 389-3:1994)*

EN ISO 389-4, *Acoustics — Reference zero for the calibration of audiometric equipment — Part 4: Reference levels for narrow-band masking noise (ISO 389-4:1994)*

EN ISO 389-8, *Acoustics — Reference zero for the calibration of audiometric equipment — Part 8: Reference equivalent threshold sound pressure levels for pure tones and circumaural earphones (ISO 389-8:2004)*

EN ISO 8253-1, *Acoustics — Audiometric test methods — Part 1: Basic pure tone air and bone conduction threshold audiometry (ISO 8253-1:1989)*

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EN ISO 8253-2, *Acoustics — Audiometric test methods — Part 2: Sound field audiometry with pure-tone and narrow-band test signals (ISO 8253-2:2009)*

EN ISO 8253-3, *Acoustics — Audiometric test methods — Part 3: Speech audiometry (ISO 8253-3:1996)*

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
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
person with hearing impairment having complete or partial loss of the ability to hear from one or both ears

NOTE The level of impairment can be mild, moderate, severe or profound.

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

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

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

3.6
hearing system
integral and customised system consisting of one or two hearing aids, ear-moulds and related components such as a remote control or interfaces to other information or communication systems

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

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

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

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

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

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

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

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

4 Service preconditions

4.1 General

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

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a) educational requirements specifying the competencies that shall be required to perform the services;

b) facility requirements specifying how the appropriate environment shall be for the proper delivery of the services;

c) equipment requirements specifying what the necessary equipment for performing the services shall be;

d) ethical recommendations specifying what the ethical framework and code of conduct should be.

4.2 Educational requirements

4.2.1 General

This subclause specifies the competencies required for performing the hearing aid provision processes that are described in Clause 5 of the service specifications.

The competencies of the persons delivering the service are very important for the quality of the service and shall be rooted in proper initial and continued 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 shall rest with a person having the educational background specified in 4.2.2.

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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 supervision of the hearing aid professional that shall be present at the premises and who remains responsible for the activities.

4.2.2 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 shall 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 European Standard the hearing aid professional shall hold qualifications recognised 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 European Qualification Framework (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 to be acquired from a sufficient education are outlined in Annex A.

4.2.3 Continued education requirements for hearing aid professionals

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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.

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

4.3 Facility requirements

4.3.1 General

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 Clause 5 the following service areas shall be available:

- reception area;
- counselling area;
- audiometry area;
- fitting area;
- maintenance area.

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The service provider shall ensure that the service is fully accessible to the clients, e.g.:

— it shall be easy to contact the service provider e.g. by telephone, SMS, telefax and/or email;

— 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. The design should also be adequate for persons with other disabilities, e.g. impaired vision and impaired mobility. It is recommended that the rooms should have low reverberation time, low ambient noise level and good lighting facilitating lip reading and sign language.

4.3.2 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 connected to a microphone and other audio sources. A waiting area should be naturally connected with the reception area and separated from the other service areas.

4.3.3 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 or other persons cannot overhear conversations between the hearing aid professional and the client.

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4.3.4 Audiometry area

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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 earphones or bone vibrators shall be measurable down to 20 dB HL for air conduction (30 dB HL bone conduction), which means that maximum ambient sound levels shall fulfil the requirements in EN ISO 8253-1, EN ISO 8253-2, and EN ISO 8253-3. This requirement can be fulfilled by a sound insulating cabin for pure tone audiometric measurements.

4.3.5 Fitting area

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 10 m^2 and a minimum volume of 25 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 40 dB under operating conditions;

— 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.