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Services offered by hearing aid professionals

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Nederlands voorwoord

Voor de in deze norm vermelde normatieve verwijzingen bestaan in Nederland de volgende equivalenten:

vermelde norm	Nederlandse norm	titel
EN 60118-4	NEN-EN-IEC 60118-4	Elektro-akoestiek - Hoortoestellen - Deel 4: Ringleidingen voor de overdracht van audiofrequenties voor hoortoesteldoeleinden - Magnetische veldsterkte
EN 60118-7	NEN-EN-IEC 60118-7	Elektro-akoestiek - Hoortoestellen - Deel 7: Meting van de prestatieskarakteristieken van de hoortoestellen voor de productie, voorziening enleveringskwaliteitsborging
EN 60645-1	NEN-EN-IEC 60645-1	Elektro-akoestiek - Audiologische apparatuur - Deel 1: Zuivere toon audiometers
EN 60645-2	NEN 10645-2	Audiometers - Deel 2: Toestellen voor spraakaudiometrie
EN 60645-5	NEN-EN-IEC 60645-5	Elektro-akoestiek - Audiometrische apparatuur - Deel 5: Instrumenten voor de metingen van akoestische impedantie/admittantie
EN 61669	NEN-EN-IEC 61669	Elektro-akoestiek - Apparatuur voor in situ metingen (r.e.m. real ear measurement) van akoestische kenmerken van hoortoestellen
EN 61672-1	NEN-EN-IEC 61672-1	Elektro-akoestiek - Geluidniveaumeters - Deel 1: Specificaties
EN ISO 389-1	NEN-EN-ISO 389-1	Akoestiek - Referentiedrempelgeluiddrukniveau voor het kalibreren van audiometrische apparatuur - Deel 1: Equivalente referentiedrempelgeluiddrukniveaus voor zuivere tonen en supra-aurale koptelefoons
EN ISO 389-2	NEN-EN-ISO 389-2	Akoestiek - Referentiegeluiddrukniveaus voor het kalibreren van audiometrische apparatuur - Deel 2: Equivalente referentie-drempelgeluiddrukniveaus voor zuivere tonen en insteektelefoons
EN ISO 389-3	NEN-EN-ISO 389-3	Akoestiek - Referentiegeluiddrukniveau voor het kalibreren van audiometrische apparatuur - Deel 3: Referentie-gehoordrempelniveaus voor zuivere tonen en beengeleiders
EN ISO 389-4	NEN-EN-ISO 389-4	Akoestiek - Referentiegeluiddrukniveau voor het kalibreren van audiometrische apparatuur - Deel 4: Referentieniveaus voor smalle-band maskeergeluid
EN ISO 389-8	NEN-EN-ISO 389-8	Akoestiek - Referentiedrempelgeluiddrukniveau voor het kalibreren van audiometrische apparatuur - Deel 8: Equivalente referentiedrempelgeluiddrukniveaus voor zuivere tonen en circumaurale koptelefoons
EN ISO 8253-1	NEN-EN-ISO 8253-1	Akoestiek - Audiometrische beproevingsmethoden - Deel 1: Algemene lucht- en beengeleidingsdrempelaudiometrie met zuivere tonen
EN ISO 8253-2	NEN-EN-ISO 8253-2	Akoestiek - Audiometrische beproevingsmethoden - Deel 2: Audiometrie met zuivere tonen en smalle band proefsignalen
EN ISO 8253-3	NEN-EN-ISO 8253-3	Akoestiek - Audiometrische beproevingsmethoden - Deel 3: Spraakaudiometrie
ISO 12124	NEN-ISO 12124	Akoestiek - Procedures voor het meten van de akoestische eigenschappen van gehoorprothesen aan het menselijk oor
ISO 16832	NEN-ISO 16832	Akoestiek - Beoordeling van luidheid door indeling in categorieën

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15927

August 2010

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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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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.

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*

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

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

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

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)*

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.

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

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

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

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:

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.

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

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.

4.3 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.

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.

4.3.4 Audiometry area

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.

4.3.6 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 shall be ensured that activities in the maintenance area do not disturb (noise, fumes, etc.) the activities in the audiometry and fitting areas.

4.4 Equipment requirements

4.4.1 General

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 subclauses.

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.

All equipment shall be CE marked.

4.4.2 Audiometric equipment

For pure-tone audiometry an audiometer shall be used for testing of air-conduction as well as bone-conduction using masking when applicable. The audiometer should be capable of measuring with earphones 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 type 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 the relevant parts of EN ISO 389.

For speech audiometry, equipment fulfilling the requirements of EN 60645-2 shall be available. Power amplifier and loudspeaker shall be available if sound field speech audiometry is performed. 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 checks these shall be applied.

4.4.3 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;

— hygienic products for hands and equipment.

4.4.4 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.

4.4.5 Electro-acoustic measurement equipment

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 with EN 60118-7 shall be available.

Furthermore, the following equipment should also be available:

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

— a class 1 or class 2 sound level meter according to EN 61672-1.

The maximum interval between calibrations of such electro-acoustic equipment shall not exceed twelve months.

4.4.6 Maintenance tools

Appropriate equipment for maintenance of hearing systems shall be available. Such equipment could comprise:

— rotary polisher for ear-mould adjustments;

— tool for drilling and trimming of tube ends;

— ultrasonic bath;

— set of screwdrivers and pliers;

— stethoscopic listening device;

— binocular magnifying glass or illuminated magnifying glass;

— vacuum pump, compressor or aerosol.

4.4.7 Demonstration tools

For demonstration of products a selection of hearing aids and accessories shall be available. Other hearing assistive devices should also be available.

An induction loop system with magnetic field in accordance with EN 60118-4 shall be available for demonstration of hearing aids with induction pick-up coil.

4.5 Ethical requirements and code of practice

4.5.1 General

The services offered by hearing aid professionals are highly important to the clients receiving the services. It is therefore imperative that every activity is provided with the goal of achieving the best possible solution for the clients. Hearing aid professionals should exercise their profession for the purpose of seeking to assist their clients by offering the best solutions for the clients' needs and preferences, e.g. communication.

The services offered by hearing aid professionals involve relationships to other service providers and the proper relationship to these other stakeholders are also important for the total service provided to the hearing impaired clients.

4.5.2 Relationship with clients

Hearing aid professionals should always bear in mind that their role is to use their knowledge and skills for the benefit of hearing impaired persons.

In their relations with clients, the hearing aid professional should be discreet and tactful, and sensitive to client's psychological and psychosocial needs. The hearing aid professional should on all occasions be cautious, calm and understanding. Clients' confidence in their hearing aid professional is an essential requirement of the profession. In their relations with clients, the hearing aid professional should make sure that their comments have been well received and understood.

The hearing aid professional should extend their service to the clients until best possible rehabilitation has been achieved. The hearing aid professional should provide all the information necessary for the correct use and maintenance of the hearing system and should give the client the instructions that are essential to ensure the continued efficacy of the system.

The hearing aid professional should not attract or try to attract clients by means of gifts or other incentives unrelated to the service, either directly or indirectly through third parties.

Where necessary and possible, the hearing aid professional should suggest that clients receive additional support that falls outside the scope of the services provided by hearing aid professionals to enable multi-disciplinary care in order to improve quality of life. Clients shall be able to freely choose any other health care professional as wished.

Hearing aid professionals should provide contact details of relevant user organisations for hearing impaired.

4.5.3 Relationship with medical practitioners

The hearing aid professional is aware that communication and hearing problems can be caused by medical conditions that require proper medical treatment. Such medical treatment falls outside the scope of the services offered by hearing aid professionals.

The hearing aid professional should never attempt in any way to replace a medical service provider. Under circumstances where the client has not previously sought medical assessment of the hearing problem, the hearing aid professional should advise the hearing impaired person seeking his services to consult an appropriate medical practitioner. This can lead to situations where multiple service providers in concert are offering multi-disciplinary care. The hearing aid professional should undertake to make available to the physician and other involved service providers all necessary and relevant documentation with consent of client.

The hearing aid professional should refrain from competition adverse arrangements that infringes the ethics of the profession. This includes collusion with medical practitioners or other third party health care professionals resulting in circumvention of normal competitive conditions.

4.5.4 Relationship with colleagues

A hearing aid professional should refrain from unjustifiable criticism of colleagues' judgement, training, knowledge or skills. A hearing aid professional should not knowingly ignore professional misconduct or incompetence.

4.5.5 Advertising

A hearing aid professional who wishes to advertise his services should of course do so. It is important that points of service are easily found by those in need of the services.

Such advertising shall be in compliance with the provisions of applicable EU directives and applicable national legislation.

5 Hearing aid provision process

5.1 General

Hearing aid provision covers assessment of the client's needs and degree of hearing loss followed by the selection and fitting of suitable hearing aids, rehabilitation and short and long term monitoring and support.

Hearing aid fitting shall consist of both the delivery of the hearing instruments, the fitting process and the related care. The efficacy of the hearing system depends on the type of device chosen, its fitting, the counselling and the follow-up.

During the entire fitting process, many decisions shall be taken in a close dialogue with the client. The availability of the proper facilities and equipment is important for a successful hearing aid provision process.

The hearing aid professional should pay particular attention to clients with no previous experience in using hearing aids.

5.2 Client contact and registration

When the client is met at the reception area it can either be by appointment or a spontaneous visit. If the client is scheduled for a hearing aid fitting the pertinent demographic data shall be recorded.

The process flow of hearing aid provision shall be explained thoroughly to the client including the financial implications. Annex C gives a comprehensive account for the information that can be given to the client.

The names and qualification of all the staff operating in the practice unit shall be readily identifiable, e.g. by a badge.

5.3 Hearing profile determination

The hearing aid professional shall do a hearing profile determination that establishes an account for the client's auditory problems, social situation, activity limitations, needs and expectations. The assessment shall also include contributing factors such as visual impairments and fine motor skill impairments. The following conditions shall be considered for the hearing profile and properly documented:

— type, degree and history of the hearing impairment;

— communication and hearing disabilities, social consequences;

— relevant living conditions, and the need for assistive listening devices, hearing expectations and individual hearing situations;

— relevant medical history including allergies and medication;

— fine motor skill impairments, visual impairments or other disabilities;

— tinnitus, dizziness and hyperacusis;

— previous use of hearing aid and other assistive devices.

The hearing profile should use the terminology of ICF (International Classification of Functioning, Disability and Health) to define the degree of hearing impairment.

NOTE It is recommended to use validated questionnaires for the recording of these factors.

5.4 Audiological assessment

5.4.1 General

An audiological assessment shall be made as an essential basis for the selection of suitable hearing systems for the individual client. All test results of the audiological assessment shall be recorded in the client file. The subclause below specify the elements of the audiological assessment.

5.4.2 Otoscopy

Otoscopy shall be carried out with examination of the external ear canal, eardrum and also pinna and area behind the ear.

5.4.3 Pure-tone audiometry

Pure-tone audiometry shall be carried out according to the procedure described in EN ISO 8253-1.

Hearing thresholds (with masking if necessary) shall be determined at least at the following frequencies:

— air conduction: 500 Hz, 1 000 Hz, 2 000 Hz, 3 000 Hz, 4 000 Hz, 6 000 Hz and 8 000 Hz;

— bone conduction: 500 Hz, 1 000 Hz, 2 000 Hz and 4 000 Hz.

5.4.4 Speech audiometry

The client's ability to recognise speech is an important parameter for the audiological assessment and shall always be considered.

When speech audiometry is performed, it shall follow the procedure specified in EN ISO 8253-3. Standardised recorded speech test material as specified in EN ISO 8253-3 shall be used, if available. The speech signal may be presented monaurally through earphones or binaurally in a sound field.

Speech presented in a background of competing noise should be used since it represents a more realistic situation than speech in quiet.

5.4.5 Other audiometric tests

If deemed relevant other audiometric tests shall be carried out. Such measurements could be:

— tympanometry, a tympanometer fulfilling the requirements in EN 60645-5 shall be used;

— loudness discomfort level (UCL) at relevant frequencies;

— most comfortable loudness (MCL) at relevant frequencies;

— loudness scaling at relevant frequencies, the procedure shall follow ISO 16832.

5.4.6 Medical referral

If the results of the audiological assessment and the hearing profile indicate a disease or other cause of the hearing loss that could need medical or surgical treatment, the hearing aid professional shall refer the client to a medical specialist.

5.5 Hearing system fitting

5.5.1 Choice of hearing system components

Based on the audiological assessment and the hearing profile the hearing aid professional shall decide what types of hearing systems would be suitable for the client. The various options in terms of models, styles, feature levels including induction pick-up coil, accessories and prices shall be presented to the client and their respective advantages and limitations described. If no contra-indications are present, bilateral fitting shall be recommended. The choice of hearing system(s) to be fitted as well as other assistive listening devices shall be based on informed consent by the client with all relevant information including the financial implications. Product and cost documentation on the proposed solution shall be given to the client.

5.5.2 Preparations for fine-tuning

Depending on the type of hearing system chosen certain preparations may be needed before the actual fitting can be carried out. If a custom mould/shell is needed for the hearing system chosen an ear impression shall be made and the proper acoustic properties of the customised part determined. The regulations of the current EC Medical Device Directive shall be adhered to.

The hearing aid professional shall enter the following data in the fitting system from the manufacturer:

— data from the audiological assessment;

— data from the hearing profile;

— properties of acoustic coupling (e.g. ear-mould).

Based on this data, a pre-setting shall be programmed into the hearing aid to be the starting point for the fine-tuning of the fitting.

5.5.3 Fine-tuning of hearing aids

The hearing system is physically placed on the client who can then verify the proper physical fit. If the fit is not accepted the custom ear-mould/shell shall be modified until proper fit is achieved.

The hearing aid is fine-tuned in close interaction with the client until a setting, accepted by the client, has been reached.

In cases where an acceptable fitting is not easily obtained, additional surveys shall be carried out to identify the ways to improve the fitting. If real-ear measurements are performed they shall follow ISO 12124.

If hearing aids with several user-selectable settings are used, the fine-tuning procedure shall be repeated for all programs, considering the specific listening situations for which they are intended to be used. This also comprises programs for telecoil and direct audio input in case the hearing aid has such features. The telecoil should be excited by the appropriate magnetic field strength (see 4.4.7).

5.5.4 Verification of fitting

To verify that a proper fitting has been achieved, steps shall be taken to test for improvement in hearing ability.

It shall be assured that no discomfort is created in particularly loud situations. The client shall be exposed to situations that likely will be part of the client's everyday life in accordance with the hearing profile. This can be accomplished by using recordings of typical real-life situations (soundscapes).

Verification of improvement in hearing ability should be assessed in multiple ways. At least one of these shall be used and the results reviewed with the client:

— speech audiometry in sound field with and without noise, aided compared to unaided, following the procedure specified in EN ISO 8253-3;

— surveys with real-ear measurements to verify that the response achieved matches the proposed fitting target, following the procedure specified in ISO 12124. Client preferences may result in deviations from the proposed target;

— questionnaire concerning the perceived benefit of the hearing system. The questions may refer to before and after fitting or focus directly on perceived benefit. A scientifically validated questionnaire should be used, and the client should have at least several weeks of everyday experience with the hearing system.

Other verification methods that can also be applied are:

— measurement of aided hearing threshold levels in sound field according to EN ISO 8253-2;

— localisation performance using loudspeaker arrays;

— presentation of relevant soundscapes.

5.5.5 Client instructions

Before the fitting process can be considered completed the client shall be given a comprehensive introduction to the hearing systems fitted and available assistive listening devices, in particular clients who have no previous experience of using a hearing aid. This shall at least include:

— product-specific instructions and demonstrations;

— instructions and demonstrations on how to place and operate the hearing aids;

— instructions and demonstrations on how to replace batteries;

— hearing tactics: teaching and training of individual behavioural patterns to cope with difficult acoustic environments;

— advise on the use of the hearing aid with induction loops or other hearing enhancement systems within buildings;

— instructions on how to clean and maintain hearing aids and ear-moulds.

If applicable the client shall be informed in writing about the possibilities for auditory training for improvement of the auditory capability.

5.6 Follow-up services

5.6.1 General

In most cases, it takes a while for the client to get used to the hearing system and to obtain full benefit of use. The client may also experience situations where the hearing system is not performing as expected. Therefore follow-up visits shall be scheduled.

The purpose of the follow-up services is to assist the client in adapting to the hearing system and if needed to perform further adjustment of the hearing aid settings. Several follow-up appointments should be included, finishing with advice on the long-term use of the hearing system.

5.6.2 Auditory training

For clients with a long history of considerable hearing loss the full benefit of the hearing aids may only be reached by means of auditory training. Such training can be provided by the hearing aid professional or by other qualified service providers.

5.6.3 Fitting follow-up

A first follow-up appointment shall be scheduled shortly after fitting verification.

The objective of this appointment is to check the hearing system fitting after the client has completed a period of adaptation in the client's everyday environment.

Conditions that shall be considered are:

— state of outer ear by otoscopy;

— physical appearance and fit;

— operational issues in use of the hearing system;

— cerumen problems;

— auditory performance.

The assessment of auditory performance should be based on ICF classification.

If needed, further adjustments of the hearing aid settings shall be performed to improve hearing system performance. Additional follow-up appointments shall be suggested to the client.

At each follow-up appointment the statements by the client and the solutions provided shall be added to the client record.

5.6.4 Maintenance

The hearing aid professional shall offer to assist the client in case of any malfunction of the hearing system. This should include testing of the hearing aid characteristics in accordance with EN 60118-7.

6 Quality management system

6.1 General

The services offered by hearing aid professionals shall be covered by a quality management system to ensure adequate hearing and communication rehabilitation utilising state of the art technical systems and audiological knowledge. The quality management system shall comprise the following elements:

— quality management objectives;

— procedures to monitor the fitting quality, and if necessary, initiate corrective measures;

— measures to ensure the client’s protection, safety and satisfaction.

It is recommended that the hearing aid professionals apply a certified quality management system according to EN ISO 9001 or EN ISO 13485.

6.2 Documentation

The hearing aid professional shall maintain a client file system where all activities and interactions with clients are recorded. More specifically the record shall include at least the following elements:

— client demographic information;

— client medical affiliations;

— client hearing profile;

— hearing system type and serial number for traceability according to Directive 93/42/EEC T;

— fitting appointments;

— fitting settings;

— fitting verification;

— follow-up adjustments;

— report to prescribing physician, if applicable.

The file system can be either paper or computer based.

The hearing aid professional shall maintain a file where all periodic checks and calibrations of equipment are documented, including results and identity of the laboratories that performed the checks.

6.3 Customer complaint handling

The hearing aid professional shall facilitate the expression and collection of complaints, for example by means of complaints files, satisfaction surveys, etc.

The service provider shall record, study and attempt to resolve (answer) all complaints received whether orally or in writing. The client filing a complaint shall be given a first response as fast as possible which should be no later than 15 working days after the filing.

6.4 Client evaluation of services

The hearing aid professional shall carry out periodical client satisfaction surveys designed to measure the client satisfaction with the services provided.

The collection of data shall be carried out by means of a satisfaction questionnaire. Survey results shall be available in the service unit.

6.5 Corrective actions

The service provider shall strive to improve the services offered taking input from client complaints as well as client evaluation of services. The areas of improvement identified shall be analysed and addressed by appropriate corrective actions.

Annex A
(normative)

Minimum competencies of the hearing aid professional

A.1 Description of competencies

This document defines the minimum competencies required from a hearing aid professional, which enables him/her to properly perform the services covered by this European Standard. The detailed specification of the competencies is composed to correspond to all the activities regulated by this standard.

An educational program for hearing aid professionals shall develop the competencies defined in the standard through a combination of theoretical and practical training.

As a guideline, a recommendation for a suitable curriculum structure for the education of hearing professionals is also included as Annex B (informative).

Certain competencies like noise protection or paediatric hearing aid fitting are not included since they do not belong to the scope of this European Standard.

A.2 General competencies

The hearing aid professional shall be capable of:

— assessing client needs;

— measuring hearing;

— selecting, adjusting and fitting of hearing systems;

— monitoring the effectiveness of the fitted system;

— counselling on the choice and use of hearing aids;

— servicing of hearing aids;

— delivering the services in dialogue with the client;

— documenting services performed and measurement results.

A.3 Audiological assessment – Hearing measurements and physical examinations

The hearing aid professional shall be capable of:

— performing otoscopy and examination of the ear;

— performing pure-tone audiometry with and without masking, air-conduction as well as bone conduction, aided and unaided;

— performing speech audiometry, in quiet and in noise, aided and unaided;

— knowledge of other relevant tests: Tympanometry, UCL, MCL & Loudness Scaling;

— identifying conditions that require medical or other professional intervention;

— interpreting documents related to the audiological assessment from prior investigations (referrals).

A.4 Hearing profile – Relevant factors beyond the audiological assessment

The hearing aid professional shall be capable of procuring and documenting information on:

— type, degree and history of the hearing impairment;

— communication and hearing disabilities, social consequences;

— relevant living conditions, hearing expectations and individual hearing situations;

— relevant medical history including allergies and medication;

— motor skill impairments;

— tinnitus, dizziness and hyperacusis;

— previous hearing aid use.

A.5 Selection, fitting, verification and provision of hearing aids

The hearing aid professional shall be capable of:

— selecting appropriate hearing aids in accordance with the results of the audiological assessment and hearing profile;

— selecting appropriate type of earpiece for the hearing aids selected;

— programming the hearing aid using the manufacturer's fitting software;

— measuring the hearing aid characteristics electro-acoustically to ensure proper functionality and suitability;

— fitting the hearing system on the clients ear and adjusting the mechanics and acoustics of the hearing aid;

— fine tuning the hearing aid in co-operation with the client;

— verifying the effectiveness of the fitted hearing aid system by appropriate methods;

— instructing the person suffering hearing loss on how to use the hearing aid.

A.6 Selection, manufacturing, modification and maintenance of ear moulds

The hearing aid professional shall be capable of:

— assessing the anatomical and physiological characteristics of the clients ear for selecting and manufacturing an ear mould;

— taking ear impressions;

— processing impressions to create a die that will be used in the manufacture of the ear moulds;

— manufacturing ear moulds with the most suitable material and shape, according to the type of device required;

— modifying ear moulds for proper physical fit;

— advising the client on cerumen management.

A.7 Modification and maintenance of hearing aids, accessories and assistive devices

The hearing aid professional shall be capable of:

— examining hearing aid for proper functionality;

— clean hearing aids and ear pieces;

— performing electro-acoustic measurements to verify functionality;

— repairing and modifying hearing aids;

— offering accessories to enhance the utility of hearing aids;

— offering assistive devices and systems to complement hearing aids.

A.8 Interaction with clients for proper rehabilitation

The hearing aid professional shall be capable of:

— applying communication, behavioural and relational patterns suitable for specific groups of population, especially for elderly people;

— establishing the psychosocial conditionings of the client as part of the general assessment prior to hearing aid service provision;

— providing the client with complete information on the steps required to carry out tests and fitting of a hearing system, the duration of the process and the financial implications;

— applying adequate counselling techniques directed to correctly manage the expectations of the client about the outcome of the rehabilitation strategy;

— providing the client and the people accompanying him/her with all of the information they require in order to handle administrative and social security documents properly;

— providing the client with relevant information about hearing tactics and supplementary systems and services that can improve the utility of the hearing system.

Annex B
(informative)

Recommendation for an appropriate organization of education and training for hearing aid professionals

A hearing aid professional should have completed an education and training programme of at least three years. The education and training programme should be distributed as shown below. Local conditions and traditions may cause variations in the organization of the education. Furthermore, a supplementary education module for managing a practice unit is also provided.

Table B.1 — Exemplary curriculum for hearing aid professionals

Exemplary curriculum for hearing aid professionals	Hours
Total	2 250
Theory	1 420
Basic knowledge	180
Mathematics, informatics, statistics	100
Physics, basic acoustics, building acoustics	40
Electronics, magnetism & signal proc.	40
Bio medicine	145
Anatomy, physiology, pathology in general and related to hearing	85
Biology, genetics	30
Neurology and other relevant medical disciplines	30
Human / Social science	170
Psychology	80
Gerontology	20
Linguistics, phonetics	50
Logopaedics	20
Audiology	245
Psycho-acoustics of impaired hearing	40
Functional audiology	40
Evaluation of hearing	40
Pediatric audiometry	30
Noise and hearing impairment	25
Medical conditions associated with hearing	70

Table B.1 *(continued)*

Hearing aid technology (from basic knowledge)	300
Acoustical measurement and calibration, general	50
Electroacoustics, transducers, tubing	100
Signal processing	100
Real ear measurements	50
Hearing rehabilitation systems	130
Hearing rehabilitation systems, air & bone conduction, implants, assistive devices	80
Composition and repairs of hearing systems	50
Otoplastics & ITE devices	90
Types & indications	30
Acoustics & vents	30
Materials & manufacturing	30
Selection and fitting of hearing systems & evaluation of fitting	160
Selection criteria, fitting methodologies, programming	80
Verification, audiometric, perceptive & questionnaires	40
Rehabilitation, instructions, hearing tactics & auditory training	40
Practical training	830
Hearing aid fitting	655
Diagnostic procedures	150
Fitting	430
Production of ear moulds and ITE (In The Ear)'s	75
Repairs	75
Repairs of hearing systems	75
Final project	100
Final project	100
Supplementary education	
Managing a hearing aid centre	340
General management	140
Responsibilities and legislation	70
Quality management	30
General studies (Economics, politics, social science)	100

Based on EUROAUDIO project in the frame of the Leonardo Da Vinci program.

Annex C
(informative)

Recommendation for client information on fitting process

The needs of the patient regarding medical, administrative and information documents are related to the main steps of hearing aid fitting procedure which are:

— welcome and information;

— tests and proposals for hearing aid fitting;

— personalization, adjustment, invoicing and follow-up.

a) Welcoming and Information:

   1) general information;

   2) practician office business name: opening hours, telephone, fax, SMS and email;

   3) introduction of the reception team and practising professionals;

   4) different types of hearing aids, qualities and flaws, limitations, primary characteristics;

   5) complementary devices, possible external links (wire connection and audioshoe, magnetic coil);

   6) principle of the tuning of different sound channels (microphone, audioshoe and magnetic coils);

   7) conditions for taking the responsibility of an appliance furnished by another professional;

   8) the development of the hearing aid fitting according to the following steps;

   9) tests and diagnosis;

   10) estimates;

   11) patient's agreement and moulding operation:

      i) mutual engagements and return conditions (for both behind or in the ear devices);

      ii) adjustment procedure and testing period;

      iii) the following-up of the hearing aid fitting;

      iv) price list and different possible financial aids;

      v) available accessories;

      vi) guarantees and maintenance unit;

      vii) items covered by the guarantee;

      viii) possible loans of hearing aids in case of repairing;

ix) insurance offers in case of breakage or loss.

b) Examinations, proposal and estimate:

1) results of audiometric tests;

2) equipment proposal and cost estimate;

3) characteristics of the hearing aid (classification on the list of refundable products, T and MT positions, feedback cancelling feature, automatic gain control and others, etc.);

4) options.

c) Adjustment, invoicing and follow-up:

1) note concerning the possibilities of complementary multidisciplinary assistance available;

2) guarantee;

3) medical file: report of examination, hearing diagnostic, fitting, adjustment, satisfaction questionnaires;

4) necessary documents for reimbursements (e.g. forms, invoices and prescription);

5) timetable of future appointments.

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