Introduction

Hearing tests with International Organization for Standardization (ISO) standards focus on accuracy and reliability in assessing individuals’ hearing abilities [1]. These standards provide a standardized framework for conducting hearing tests, making it more reliable to compare results across different clinics, researchers, and countries. Obtaining accurate test results is one of the important parts of audiology and contributes to diagnosing hearing loss and determining appropriate interventions.

Hearing tests play a pivotal role in assessing individuals’ auditory capabilities and identifying potential hearing impairments. Evaluation of individual hearing threshold levels across different frequencies with hearing tests provides valuable insights into the functioning of the auditory system. Early detection of hearing loss is essential for timely intervention, as untreated hearing impairments can have significant social,
also contributed to promoting speech audiometry and intensity scales without standard reference levels [6]. Fletcher audiometer and it was operated with limited frequency and R.L. Wegel in 1923 was the first widely used commercial innovative and collaboration among professionals in the field, enabling the exchange of data, research findings, and best practices. Moreover, the standards provide a foundation for benchmarking and monitoring trends in hearing health on a broader scale, contributing to the development of evidence-based interventions, public health policies, and quality assurance in audiological care. Ultimately, the implementation of standard in hearing testing ensures that individuals receive consistent and reliable evaluations of their hearing abilities, enabling appropriate interventions and support tailored to their specific needs.

**Development of International Standards for Hearing Tests**

The Western Electric 2-A developed by Harvey Fletcher and R.L. Wegel in 1923 was the first widely used commercial audiometer and it was operated with limited frequency and intensity scales without standard reference levels [6]. Fletcher also contributed to promoting speech audiometry and developed a method in 1929 [7]. The unstandardized calibration of audiometers led to the "Beasley Survey" conducted by the United States Public Health Service (USPHS) in 1935, providing data on average normal hearing thresholds across frequencies from 128 Hz to 8,192 Hz. In 1951, the American Standards Association (ASA) published the ASA-1951 standard, establishing the 0 dB threshold line in sound pressure level (SPL) at each frequency, gaining global recognition [8].


Other ISO standards related to pure-tone audiometry include ISO 389 (1976), which focused on audiometer calibration. ISO 389 is a series of standards that deal with several essential aspects of hearing tests including reference of hearing threshold scales, testing environments, and calibration [12-20]. ISO 389-1 and ISO 389-2 specify the standard reference zeros for the scale of hearing threshold level applicable to pure-tone air conduction audiometers with supra-aural and insert earphones, respectively [12,13]. ISO 389-3 specifies the standard reference zero for the scale of hearing threshold level applicable to pure-tone bone-conduction audiometry [14]. ISO 389-4 specifies the reference levels of narrow-band masking noise [15]. ISO 389-5 specifies the reference equivalent threshold sound pressure levels for pure tones in the frequency range 8 kHz to 16 kHz [16]. ISO 389-6 specifies the reference threshold of hearing for short duration test signal [17]. ISO 389-7 specifies a reference threshold of hearing for the calibration of audiometric equipment used under specific listening conditions [18]. Finally, ISO 389-8 specifies a reference equivalent threshold sound pressure levels for pure tones and circumaural earphones [19]. In addition, ISO 389-9 specifies the preferred test conditions for determination of reference hearing threshold levels [20].

The International Electrotechnical Commission (IEC) focuses on standardizing various aspects of electrical and electronic technologies, including medical equipment used in audiology and hearing assessment [21-26]. While the ISO 389 and 8253 series of standards primarily address hearing measurement and assessment methods, the IEC standards deal with requirements and calibration methods of equipments such as audiometer [21-23], impedance audiometers [24], oto-
Pure-tone audiometry in ISO and IEC standards

ISO 8253-1 consists of procedures and requirements for pure-tone audiometry [1]. Air conduction audiometry involves presenting the test signal through earphones, while bone conduction audiometry uses a bone vibrator placed on the mastoid or forehead. It is recommended to start with air conduction measurements followed by bone conduction measurements. Threshold levels can be determined using fixed-frequency audiometry or sweep-frequency audiometry. Both ears’ hearing threshold levels should be determined separately, and masking noise may be applied to the non-test ear under specified conditions.

The calibration of audiometric equipment follows the standard reference zero in ISO 389 series [12-20], and equipment requirements are outlined in IEC 60645-1 [21]. Qualified testers or those under their supervision should conduct the tests, and care should be taken to prevent subject fatigue. The test environment conditions, including ambient sound pressure level, are specified, and the uncertainty of measurement results should be evaluated according to ISO/IEC Guide 98-3 [33].

ISO 8253-1 focuses on the preparation and instruction of test subjects before audiometric testing and the correct positioning of transducers. It emphasizes avoiding recent noise exposure and allowing subjects to arrive early to minimize errors. An otoscopic examination and preliminary tuning fork tests are recommended to assess hearing loss and masking requirements. Clear and appropriate instructions should be given to the subjects, specifying the response task and the importance of remaining still. Proper placement of transducers, such as earphones and bone vibrators, is crucial for accurate testing.

The procedure for determining air conduction hearing threshold levels using fixed-frequency audiometry involves presenting test tones manually or with an automatic-recording audiometer. The specific order of test tones should be followed, starting from 1,000 Hz and going upwards, followed by the lower frequency range. Threshold measurements are performed with and without masking noise. Two methods are specified for threshold measurements without masking: ascending method and bracketing method. For threshold measurements with masking, masking noise is applied to the non-test ear if necessary.

Estimation of hearing threshold level is done by determining the lowest level at which responses occur in more than half of the ascents for the ascending method and averaging the lowest levels of responses in ascents and descents separately, then calculating the mean of these two averages for the bracketing method. ISO 8253-1 also briefly mentions procedures for automatic recording audiometry, computer-controlled threshold determination, sweep-frequency audiometry for air conduction threshold measurements, and bone conduction hearing threshold audiometry. It provides guidelines for bone conduction testing and masking procedures in bone conduction audiometry. Additionally, it covers guidelines for screening audiometry, both manually controlled and computer-controlled, for determining pass or fail results in screening tests.

Speech audiometry in ISO 8253-3

Speech audiometry is used for diagnostic evaluation and audiological rehabilitation. In order to ensure minimum requirements of precision and comparability between different test procedures including speech recognition tests in different languages, ISO 8253-3 specifies requirements for the composition, validation and evaluation of speech test materials, and the realization of speech recognition tests. It provides procedures for presenting recorded speech test material through earphones or loudspeakers. Methods for using noise for masking or as competing sound are described.

ISO 8253-3 also provides guidelines for test preparation, instructions to the subject, response modes, and intervals between test items in speech audiometry. Prior to speech audiometry, pure-tone audiometry is assumed to have been conducted. Preparation includes an otoscopic examination and confirming the subject's understanding and ability to reproduce the test material. Clear instructions of the tester with an appropriate language are necessary and the subject’s response can be spoken, written, or indicated through a keyboard.

ISO 8253-3 specifies the procedure for determining the speech detection threshold level during monaural testing. The procedure involves using connected speech as the speech signal and starting with a high level, approximately 30 dB above the average of the subject’s pure-tone hearing threshold levels at 500 Hz, 1,000 Hz, and 2,000 Hz. The level is then decreased in 20 dB steps until the subject no longer responds and then increased in 5 dB steps until the subject responds. To determine the speech recognition threshold level, the procedure involves using complete test lists of single words, phrases, or
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• Preparation and education of subjects, headphone/bone vibrator use  
• Hearing measurement, uncertainty evaluation methods                                                                 | KSISO8253-1          |
|                               |              | Part 1: Pure-tone air and bone conduction audiometry                  |                                                                                               |                      |
• Maintenance and calibration methods  
• Explanation of signal sounds that can be used  
• Examination environment (characteristics, settings, permissible ambient noise range), preparation and education of subjects, and reporting of results                                                                 | KSISO8253-2          |
|                               |              | Part 2: Sound field audiometry with pure-tone and narrow-band test signals |                                                                                               |                      |
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• Recording methods for speech data (recording equipment, standard recording, speech data, verification, documentation)  
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• Reporting of results, measurement uncertainty evaluation methods                                                                 | KSISO8253-3          |
|                               |              | Part 3: Speech audiometry                                             |                                                                                               |                      |
| Reference zero to the calibration of audiometric equipment | ISO 389-1 [12] | Acoustics — Reference zero for the calibration of audiometric equipment | • Specifies the reference threshold level (RETSPL) for calibrating headphones  
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*Simulated ear canal: an acoustic characteristic that simulates the average person’s ear acoustic characteristics and is generally used to calibrate headphones                                                                 | KSISO389-1          |
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<td>ISO 389-9 [20]</td>
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<td>• Equipment usage and environmental conditions</td>
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<td>• Audiogram format displayed on the equipment</td>
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<td>IEC 60645-6 [25]</td>
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<td>Electroacoustics — Audiometric equipment</td>
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<td>KSCIEC60645-7</td>
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<td>Part 7: Instruments for the measurement of auditory brainstem responses</td>
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<td></td>
<td>• Calibration method of its acoustical transfer impedance and its expanded uncertainty</td>
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<td>IEC 60318-4 [29]</td>
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<td>Electroacoustics — Simulators of human head and ear</td>
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<td>Part 4: Occluded-ear simulator for the measurement of earphones coupled to the ear by means of ear inserts</td>
<td>• Structure, headphone connection method</td>
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In speech audiometry, avoid repeating test items in the same session and present a complete test list. Determine the speech recognition threshold beforehand or familiarize the subject with test items at an audible level. Choose appropriate test levels based on the purpose of the assessment (maximum speech recognition score, speech recognition score, half-open threshold). Express scores as percentages and record the achieved level. Use contralateral masking to prevent speech signals from reaching the non-test ear during monaural speech audiometry, adjusting masking level as needed for accuracy.

During testing speech audiometry with competing sounds, the recommended speech level is 65 dB, which corresponds to the achieved level. Use contralateral masking to prevent speech signals from reaching the non-test ear during monaural speech audiometry, adjusting masking level as needed for accuracy.

Table 1. International standards for hearing tests (continued)

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<td>Electroacoustics — Simulators of human head and ear</td>
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<tr>
<td>IEC 60318-6</td>
<td>(31)</td>
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<td>Specifies the artificial mastoid used as a coupler for calibrating bone vibrators</td>
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<td>IEC/TS 60318-7</td>
<td>(32)</td>
<td>Electroacoustics — Simulators of human head and ear</td>
<td>DEScribes a head and torso simulator, or manikin, intended for the measurement of air-conduction hearing aids</td>
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Tympanometry in IEC 60645-5

Middle ear examination or aural acoustic admittance measurement including tympanometry, acoustic reflex test, acoustic reflex decay test, and Eustachian test does not require a patient's behavioral response, is inexpensive and has a very short measurement time. It is an important component of the audiological test battery and is a physiological measure that must be included in any comprehensive audiological assessment. The purpose of tympanometry is to indirectly evaluate the function of middle ear by measuring aural acoustic admittances with a probe to the ear canal attached. This test can be evaluated with a probe to the ear canal attached. This test can be evaluated with a probe to the ear canal attached. This test can be evaluated with a probe to the ear canal attached. This test can be evaluated with a probe to the ear canal attached. This test can be evaluated with a probe to the ear canal attached.
test can be performed using a single pure tone, multi-frequency stimulation, or broadband stimulation.

IEC 60645-5 specifies the calibration of aural acoustic immittance instruments. The standard includes procedures for calibrating instruments that measure admittance, impedance, reflectance, and absorbance. The standard also specifies procedures for calibrating instruments that measure acoustic reflex thresholds and decay times. According to the newest international and national standards (IEC 60645-5 [2004], ANSI S3.39-1987 [R2012]), the aural acoustic immittance instrument basically includes six components: 1) calibration cavity, 2) acoustic immittance analysis system, 3) probe assembly/unit and signal, 4) pneumatic air-pressure pump system, 5) acoustic reflex activator system, and 6) tympanogram and acoustic reflex plotting system, each of these components should meet set standards. This standard covers instruments designed primarily for the measurement of acoustic impedance/admittance in the human external acoustic meatus using a stated probe tone. It is recognized that other probe signals may also be used. The standard defines the characteristics to be specified by the manufacturer, lays down performance specifications for three types of instruments, and specifies the facilities to be provided on these types. This standard describes methods of test to be used for approval testing and guidance on methods for undertaking routine calibration. The purpose of this standard is to ensure that measurements made under comparable test conditions with different instruments complying with the standard will be consistent.

Otoacoustic emissions in IEC 60645-6

OAE testing is a non-invasive and objective method used to assess the function of the inner ear. It measures sound pressure levels in eardrum representing the outer hair cells’ responses with or without sound stimulation. OAE testing is widely used for various purposes for early screening, accurate diagnosis, and monitoring of hearing health in various populations. It includes testing newborn hearing screening, assessing individual’s hearing loss (especially for in infants and individuals with communication difficulties), monitoring hearing health, identifying cochlear pathologies, and identifying auditory neuropathy/dys-synchrony [34,35].

IEC 60645-6 pertains to instruments primarily designed for measuring OAE, elicited by acoustic probe stimuli. The standard defines the characteristics to be specified by the manufacturer, specifies minimum mandatory functions for two types of instruments, and provides performance specifications applicable to both instrument types. The standard describes methods to be used to demonstrate conformance with the specifications in this document and guidance on methods for periodic calibration.

Recent notable technical changes in IEC 60645-6:2022 include defining the nominal test frequency for distortion product otoacoustic emissions (DPOAE) as the higher of the two frequencies, f2, allowable deviation of the stimulus signal for TEOAE, the frequency range for DPOAE stimulus signals, the stimulus level requirements for TEOAE/DPOAE, harmonic distortion requirements for DPOAE, and a minimum measurement range for DPOAE.

Auditory brainstem response in IEC 60645-7

ABR test is an objective electrophysiological method used to assess hearing function and neural responses to sound stimuli. ABR measures the electrical activity of the auditory nerve and brainstem in response to sounds, providing information about hearing thresholds and neural integrity [34]. It is used in newborn hearing screening, threshold estimation, and diagnosing auditory neuropathy. ABR test serves as a critical tool in universal newborn hearing screening programs, aiding in the early identification of hearing loss in infants. Estimating hearing thresholds with ABR is particularly valuable for patients who cannot provide consistent behavioral responses or are difficult to test, such as young children or those with developmental disabilities. Additionally, ABR test plays a crucial role in diagnosing auditory neuropathy/dys-synchrony, a condition characterized by impaired neural transmission despite normal cochlear function. Furthermore, during certain surgeries involving the brainstem, ABR is utilized for intraoperative monitoring, ensuring the safety and protection of the auditory pathway. With its objective and reliable measurements of neural responses to sound stimuli, ABR significantly contributes to the accurate diagnosis, monitoring, and intervention decisions in the field of audiology.

IEC 60645-7 applies to instruments designed for the measurement of evoked potentials from the inner ear, the auditory nerve and the brainstem, evoked by acoustic and/or vibratory stimuli of short duration. IEC 60645-7 defines the characteristics to be specified by the manufacturer, specifies performance requirements for two types of instrument, screening and diagnostic, and specifies the functions to be provided on these types. The purpose of IEC 60645-7 is to ensure that measurements made under comparable test conditions with different instruments complying with this standard will be consistent. It is not intended to restrict development or incorporation of new features, nor to discourage innovative approaches. The application of electric stimuli for special purposes is beyond the scope of this standard.
Devices to simulate the auditory system in IEC 60318

IEC 60318 series specify the devices to simulate the response of human auditory system and these devices are employed to calibrate the output level of audiometer with each transducer. For the air-conduction audiometry, two types of devices, ear simulators and acoustic coupler, are defined.

Ear simulator is the device designed to have the overall acoustic impedance of the device approximates that of the normal human ear [27]. IEC 60318-1 specifies the requirement and its calibration method of ear simulators for supra-aural earphones [27]. The requirement of occluded-ear simulators for earphones coupled to the ear by means of ear inserts is specified in IEC 60318-4 [29]. The basic requirement is given in terms of the acoustical transfer impedance and its permissible deviation is also specified in the related standards.

Acoustic coupler is a device designed to have a cavity of predetermined shape and volume, which does not necessarily approximate the acoustical impedance of the normal human ear. IEC 60318-3 and IEC 60318-5 specify the required dimensions and connection method for supra-aural and ear-insert earphones, respectively [28,30].

For calibrating the bone conduction stimuli, the mechanical coupler simulating the mechanical impedance of mastoid position is employed and the reference mechanical impedance and permissible deviation are specified in IEC 60318-6 [31]. The basic method and condition for calibration of bone vibrator are also described in this standard.

IEC TS 60318-7 describes the requirement of the head and torso to simulate the auditory response including the effect of head and shoulder in free-field or specific room condition [32]. This standard specifies the geometrical dimensions and acoustical properties of system. These types of devices are not directly required to calibrate the audiometric devices for clinical purpose; however, it can be applied for the investigation concerning various practical situations.

Benefits and Challenges of International Standards

Benefits of using international standards in hearing testing

Improving test accuracy and reliability

International standards for various hearing tests establish guidelines for equipment calibration, test procedures, and verification methods. By adhering to these standards, healthcare professionals can ensure the accuracy and reliability of their testing equipment, leading to high-quality and trustworthy results.

Ensuring consistency and comparability of results

ISO and IEC standards ensure that hearing tests are conducted in a consistent manner, regardless of the different testing places or healthcare providers. Measurement consistency in hearing tests allows for improved comparability of test results across different clinics, researchers, and countries, accurate assessments, and treatment decisions.

Improved patient care

By following standards, healthcare providers can enhance the quality of patient care. Standardized protocols help ensure that hearing tests are administered correctly, minimizing errors and inconsistencies. Accurate and reliable test results aid in making appropriate diagnoses, developing personalized treatment plans, and monitoring the effectiveness of interventions over time.

Facilitating international collaboration and research

ISO and IEC standards are globally recognized and accepted. This recognition promotes interoperability and harmonization of hearing test practices across different countries and healthcare systems. It facilitates collaboration, research, and the exchange of information among professionals working in the field of audiology. Those standards provide a foundation for research and development in the field of hearing testing. They provide a common language and framework for researchers to compare and analyze data, fostering advancements in diagnostic techniques, treatment modalities, and technological innovations. These standards may be required or recommended by regulatory bodies and accreditation organizations. Adhering to these standards helps healthcare facilities and professionals comply with regulatory requirements, ensuring adherence to best practices and quality standards in hearing testing.

Challenges and limitations associated with ISO/IEC standards

Potential variations in equipment and calibration

While ISO/IEC standards for hearing testing bring numerous benefits, there are also challenges and limitations associated with their implementation. One significant challenge is the potential for variations in equipment and calibration across different clinics, manufacturers, and regions. Despite standardization efforts, there may still be differences in audiometric equipment and calibration procedures used by different providers. These variations can impact the accuracy and comparability of test results, leading to discrepancies in diagnoses and treatment decisions. Another limitation is the need for
ongoing updates and revisions of ISO/IEC standards to keep pace with advancements in technology and research. As new equipment and testing methods emerge, standards may need to be updated to ensure their relevance and effectiveness. However, the process of updating standards can be time-consuming and may lag behind technological advancements, leading to potential gaps between current practice and standard requirements. Additionally, the adoption and adherence to ISO/IEC standards may vary across different healthcare settings and regions. Some clinics or countries may have limited resources or awareness of the standards, resulting in inconsistent implementation. This variation can affect the consistency and comparability of test results, hindering international collaboration and data exchange.

Moreover, ISO standards primarily focus on technical aspects of hearing testing and may not address all clinical considerations. Audiologists and healthcare providers need to consider individual patient factors, such as medical history, communication needs, and cognitive abilities, which may not be explicitly covered in the standards. Clinical judgment and expertise are still essential in the interpretation and application of test results.

Furthermore, ISO standards may not fully address cultural and linguistic diversity in patient populations. Different languages, dialects, and cultural norms can influence the administration and interpretation of hearing tests. Adapting the standards to accommodate these diversities can be challenging and may require additional guidelines or recommendations.

Consideration of regional and cultural factors

Regional and cultural factors are crucial to consider when implementing ISO standards in hearing testing. These factors can affect how hearing tests are conducted, interpreted, and accepted in different populations. Here are some key considerations.

Language barriers can affect the administration and interpretation of hearing tests. Healthcare providers should ensure effective communication with patients who have limited proficiency in the dominant language. They should use translation services or interpreters, and provide test instructions, materials, and communication that are culturally sensitive and accessible to diverse linguistic backgrounds.

Cultural norms and beliefs may influence individuals’ attitudes towards hearing health and their willingness to participate in testing. Understanding cultural perspectives on hearing loss, stigma, and help-seeking behavior can help healthcare providers tailor their approach to testing and counseling. Sensitivity to cultural practices, taboos, and religious beliefs is essential to establish trust and foster open communication.

Environmental factors, such as ambient noise levels or testing room characteristics, may vary across different regions and healthcare settings. Adhering to ISO standards for ambient noise control is essential, but additional considerations may be needed to account for regional variations. Local norms and practices regarding test conditions and patient positioning should also be taken into account to ensure patient comfort and accurate test results.

Consideration should be given to the appropriateness of test materials and stimuli for specific cultural contexts. For example, certain frequency ranges or speech sounds may have different significance or salience in different languages or cultural groups. Adapting test materials to reflect the language, dialect, or specific sound characteristics of the population being tested can improve the validity and reliability of results. Healthcare providers should receive training on cultural competence and diversity to better understand and address the needs of diverse patient populations. This training can enhance their ability to adapt testing procedures, communicate effectively, and provide culturally sensitive counseling and support.

Conclusion

Following ISO and IEC standards in hearing tests improves accuracy and reliability of test results by applying consistent methods and environments. They provide a comprehensive framework for designing, calibrating, and assessing hearing test instruments, as well as conducting both subjective and objective hearing tests. Adherence to these standards allows hearing professionals to confidently measure and interpret results, mitigating the impact of various complex factors. Regular calibration checks and instrument maintenance ensure precise results, fostering trust in hearing test outcomes.

Moreover, these globally recognized standards promote international harmonization and data interoperability, facilitating information exchange and research collaboration across borders. Comparing findings from different locations enhances understanding of hearing-related issues and improves treatment strategies.

Additionally, adapting ISO or IEC guidelines to a country’s context and language enhances their applicability and local acceptance. Customization addresses cultural factors and unique healthcare challenges while preserving the core principles of the original standards. Striking a balance between customization and maintaining compatibility with international benchmarks ensures alignment with global best practices and supports collaboration in research and advancements.

Therefore, following international standards in hearing...
tests is essential for ensuring the quality and reliability of hearing assessment and treatment across different settings and populations.

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Conflicts of Interest
The authors have no financial conflicts of interest.

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