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Improving Accuracy and Reliability of Hearing Tests: An Exploration of International Standards

Michelle J. Suh[1], Jihyun Lee[2], Wan-Ho Cho[3], In-Ki Jin[4], Tae Hoon Kong[2], Soo Hee Oh[5], Hyo-Jeong Lee[6], Seong Jun Choi[7], Dongchul Cha[8,9], Kyung-Ho Park[10], and Young Jun Seo[2]

[1]Department of Otorhinolaryngology, Jeju National University College of Medicine, Jeju, Korea
[2]Department of Otorhinolaryngology, Yonsei University Wonju College of Medicine, Wonju, Korea
[3]Division of Physical Metrology, Korea Research Institute of Standards and Science, Daejeon, Korea
[4]Division of Speech Pathology and Audiology, Research Institute of Audiology and Speech Pathology, College of Natural Sciences, Hallym University, Chuncheon, Korea
[5]Department of Audiology and Speech Language Pathology, Hallym Univesity of Graduate Studies, Seoul, Korea
[6]Department of Otorhinolaryngology-Head and Neck Surgery, Hallym University College of Medicine, Anyang, Korea
[7]Department of Otorhinolaryngology-Head and Neck Surgery, Soonchunhyang University Cheonan Hospital, Soonchunhyang University College of Medicine, Cheonan, Korea
[8]Healthcare Lab, Naver Corporation, Seongnam, Korea
[9]Healthcare Lab, Naver Cloud Corporation, Seongnam, Korea
[10]Department of Otorhinolaryngology, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea

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Address for correspondence
Young Joon Seo, MD, PhD
Department of Otorhinolaryngology,
Yonsei University
Wonju College of Medicine,
20 Ilsan-ro, Wonju 26426, Korea
Tel +82-33-741-0644
Fax +82-33-732-8287
E-mail okas2000@hanmail.net

This study explores the internal standards for hearing tests and benefits of implementing international standard protocols, including the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC), and discusses how ISO and IEC standards provide a framework for designing, calibrating, assessing hearing test instruments and methods, and exchanging and comparing data globally. ISO and IEC standards for hearing tests improve accuracy, reliability, and consistency of test results by applying standardized methods and environments. Moreover, they promote international harmonization and data interoperability, enabling information exchange and research collaboration. Those standards for hearing tests are beneficial but have challenges and limitations, such as variation in equipment and calibration, lag in updating standards, variation in implementation and compliance, and lack of coverage of clinical aspects, cultural diversity, and linguistic diversity. These affect the quality and interpretation of test results. Adapting ISO or IEC standards locally would improve their applicability and acceptability, while balancing customization and compatibility with global standards.

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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,

emotional, and cognitive implications [2]. Furthermore, hearing tests are not only relevant for clinical purposes but also play a vital role in occupational health and safety, ensuring that individuals are fit for specific job requirements that involve auditory communication or exposure to high noise levels [3-5].

The standardized hearing tests facilitate effective communication 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].

The ISO-64 standard was introduced in 1964, providing a zero-line reference for audiometer calibration and aligning with the ASA-1951. In 1969, the American National Standards Institute (ANSI) refined the ISO-64 and released the ANSI-69 standard, resolving the transition period between ASA-1951 and ISO-64. The current ISO standard for pure-tone audiometry is ISO 8253-1, first published in 1983, specifying general requirements, calibration procedures, and verification methods for pure-tone audiometers [9]. In the United Kingdom, the British Society of Audiology (BSA) publishes recommended procedures for pure-tone audiometry, aligned with ISO standards. The American Speech-Language-Hearing Association (ASHA) published "Guidelines for Manual Pure-Tone Threshold Audiometry" in 2005 in the United States.

ISO 8253 is a series of standards for audiometric test methods. ISO 8253-1 specifies procedures and requirements for pure-tone air conduction and bone conduction threshold audiometry, including the maximum permissible ambient noise levels in audiometric rooms (ISO 8253-1: first edition in 1989, second edition in 2010) [1]. ISO 8253-2 specifies sound field audiometry with pure-tone and narrow-band test signals presented by means of one or more loudspeakers, including the maximum permissible ambient noise levels in audiometric rooms (ISO 8253-2: first edition in 1989, second edition in 2009) [10]. ISO 8253-3 specifies speech audiometry (ISO 8253-3: first edition in 1998, second edition in 2012, third editionin 2022) [11]. Both ISO 8253-1 (2010) and ISO 8253-2 (2009) are standards for audiometric test methods. The establishment of standardized calibration protocols, such as ASA-1951, ISO-64, ANSI-69, and ANSI-96, has contributed to consistent and comparable hearing test results, ensuring accurate assessments and facilitating effective patient care.

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-

acoustic emissions (OAE) [25], and auditory brainstem response (ABR) test systems [26]. The requirements and specification of devices to simulate the human ear and head, which are applied to calibrate the hearing test equipment, are also specified in IEC 60318 series [27-32]. The list of international standards related to the hearing test is summarized in Table 1.

Overview of International Standards for Hearing Tests

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

Table 1. International standards for hearing tests

Category	No.	Title	Contents	Korean standard (KS)
Audiometric test method	ISO 8253-1 [1]	Acoustics — Audiometric test methods Part 1: Pure-tone air and bone conduction audiometry	• Pure-tone bone conduction audiometry methods (threshold determination, masking, automatic audiometry, screening) • Maintenance and calibration methods • Qualifications for examiners, environmental conditions (location of subject and examiner, temperature, permissible ambient noise range) • Preparation and education of subjects, headphone/bone vibrator use • Hearing measurement, uncertainty evaluation methods	KSIISO8253-1
	ISO 8253-2 [10]	Acoustics — Audiometric test methods Part 2: Sound field audiometry with pure-tone and narrow-band test signals	• Methods for sound field 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	KSIISO8253-2
	ISO 8253-3 [11]	Acoustics — Audiometric test methods Part 3: Speech audiometry	• Methods for speech audiometry (threshold determination, masking, etc.) • Maintenance and calibration methods • Recording methods for speech data (recording equipment, standard recording, speech data, verification, documentation) • Examination environment (settings, permissible ambient noise range), subject preparation and education • Reporting of results, measurement uncertainty evaluation methods	KSIISO8253-3
Reference zero to the calibration of audiometric equipment	ISO 389-1 [12]	Acoustics — Reference zero for the calibration of audiometric equipment Part 1: Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones	• Specifies the reference threshold level (RETSPL) for calibrating headphones • Types of headphones • Method for fixing headphones to a simulated ear canal *Simulated ear canal: an acoustic characteristic that simulates the average person's ear acoustic characteristics and is generally used to calibrate headphones	KSIISO389-1
	ISO 389-2 [13]	Acoustics — Reference zero for the calibration of audiometric equipment Part 2: Reference equivalent threshold sound pressure levels for pure tones and insert earphones	• Specifies the RETSPL for calibrating insert earphones (ER-3A) • Method for connecting insert earphones to a coupler	KSIISO389-2
	ISO 389-3 [14]	Acoustics — Reference zero for the calibration of audiometric equipment Part 3: Reference equivalent threshold vibratory force levels for pure tones and bone vibrators	• Specifies the RETSPL for calibrating bone vibrators	KSIISO389-3

Table 1. International standards for hearing tests (continued)

Category	No.	Title	Contents	Korean standard (KS)
	ISO 389-4 [15]	Acoustics — Reference zero for the calibration of audiometric equipment Part 4: Reference levels for narrow-band masking noise	• Specifies the standard level for calibrating masking noise	KSIISO389-4
	ISO 389-5 [16]	Acoustics — Reference zero for the calibration of audiometric equipment Part 5: Reference equivalent threshold sound pressure levels for pure tones in the frequency range 8 kHz to 16 kHz	• Specifies the RETSPL for calibrating headphones or earphones • Types of headphones and earphones	KSIISO389-5
	ISO 389-6 [17]	Acoustics — Reference zero for the calibration of audiometric equipment Part 6: Reference threshold of hearing for test signals of short duration	• Specifies the standard level for calibrating short signals such as click sounds	N/A
	ISO 389-7 [18]	Acoustics — Reference zero for the calibration of audiometric equipment Part 7: Reference threshold of hearing under free-field and diffuse-field listening conditions	• Specifies the standard level for calibrating loudspeakers	KSIISO389-7
	ISO 389-8 [19]	Acoustics — Reference zero for the calibration of audiometric equipment Part 8: Reference equivalent threshold sound pressure levels for pure tones and circumaural earphones	• Specifies the reference threshold level (RETSPL) for calibrating circumaural earphones	N/A
	ISO 389-9 [20]	Acoustics — Reference zero for the calibration of audiometric equipment Part 9: Preferred test conditions for the determination of reference hearing threshold levels	• Specifies the preferred test condition including environmental and ambient condition for the determination of reference hearing threshold levels	N/A
Audiometric equipment	IEC 60645-1 [21]	Electroacoustics — Audiometric equipment Part 1: Equipment for pure-tone and speech audiometry	• Requirements and specifications for each type of audiometer and verification criteria • Measured signals, transducers (headphones, bone vibrators, etc.), level adjustment, reference sound • List of standards for calibration • Audiogram format displayed on the equipment	KSCIEC60645-1A

Table 1. International standards for hearing tests (continued)

Category	No.	Title	Contents	Korean standard (KS)
	IEC 60645-2 [22] (withdrawn and replaced by IEC 60645-1:2017)	Audiometers — Part 2: Equipment for speech audiometry	• Requirements and specifications for each type of audiometer	KSCIEC60645-2A
	IEC 60645-3 [23]	Electroacoustics — Audiometric equipment Part 3: Test signals of short duration	• Types and characteristics of short signals • Calibration and measurement methods for short signals	KSCIEC60645-3A
	IEC 60645-5 [24]	Electroacoustics — Audiometric equipment Part 5: Instruments for the measurement of aural acoustic impedance/ admittance	• General specifications and verification criteria, items that manufacturers must specify • Calibration methods (cavity specifications, probe connection method, expanded uncertainty) • Equipment usage and environmental conditions • Audiogram format displayed on the equipment	KSCIEC60645-5A
	IEC 60645-6 [25]	Electroacoustics — Audiometric equipment Part 6: Instruments for the measurement of otoacoustic emissions	• General specifications, essential functions, verification criteria, items that manufacturers must specify • Routine calibration methods, equipment usage and environmental conditions	KSCIEC60645-6
	IEC 60645-7 [26]	Electroacoustics — Audiometric equipment Part 7: Instruments for the measurement of auditory brainstem responses	• Auditory brainstem response (ABR) device types, general specifications, quality assurance system, verification criteria • Calibration parameters, environmental conditions	KSCIEC60645-7
Simulators of human head and ear	IEC 60318-1 [27]	Electroacoustics — Simulators of human head and ear Part 1: Ear simulators for the calibration of supra-aural earphones	• Specifies the requirements of ear simulator having the overall acoustic impedance of the device approximates that of the normal human ear for calibrating supra-aural earphones • Structure, headphone connection method • Calibration method of its acoustical transfer impedance and its expanded uncertainty	KSCIEC60318-1
	IEC 60318-3 [28]	Electroacoustics — Simulators of human head and ear Part 3: Acoustic coupler for the calibration of supra-aural earphones used in audiometry	• Specifies the acoustic coupler for the measurement of supra-aural audiometric earphones • Structure, headphone connection method	KSCIEC60318-3
	IEC 60318-4 [29]	Electroacoustics — Simulators of human head and ear Part 4: Occluded-ear simulator for the measurement of earphones coupled to the ear by means of ear inserts	• Specifies the simulated ear canal used as a coupler for calibrating ear insert earphones • Structure, headphone connection method	KSCIEC60318-4

Table 1. International standards for hearing tests (continued)

Category	No.	Title	Contents	Korean standard (KS)
	IEC 60318-5 [30]	Electroacoustics — Simulators of human head and ear Part 5: 2 cm^3 coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts	• Specifies the 2 cm^3 coupler used for calibrating insert earphones or verifying hearing aid output • Structure, insert earphone or hearing aid connection method, and expanded uncertainty	KSCIEC60318-5
	IEC 60318-6 [31]	Electroacoustics — Simulators of human head and ear Part 6: Mechanical coupler for the measurement of bone vibrators	• Specifies the artificial mastoid used as a coupler for calibrating bone vibrators • Structure, bone vibrator connection method • Calibration method of its mechanical impedance and its expanded uncertainty	KSCIEC60318-6
	IEC/TS 60318-7 [32]	Electroacoustics — Simulators of human head and ear Part 7: Head and torso simulator for the measurement of air-conduction hearing aids	• Describes a head and torso simulator, or manikin, intended for the measurement of air-conduction hearing aids • Specifies the manikin in terms of both its geometrical dimensions and its acoustical properties	KSCIECTS60318-7

sentences and descending procedures with step sizes of 5 dB and 2 dB. Adaptive procedures using fixed step sizes are also described.

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-optimum speech level). 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 sound, the recommended speech level is 65 dB, which corresponds to normal speech level in conversation. The level of the competing sound can be fixed or variable, with a recommended fixed noise level of 60 dB or variable levels changed in steps of 5 dB or less. Additionally, this standard discusses two methods for assessing speech recognition scores with competing sounds. The first method involves determining the score at a fixed speech-to-noise ratio, where the equipment is set to the required speech level, and the subject is familiarized with test items at a low competing sound level. The score is calculated as a percentage based on the desired competing sound level. The second method is for measuring the speech recognition threshold with a competing sound of varying loudness. It includes increasing the competing sound level gradually while presenting test items until the subject incorrectly recognizes one item. The threshold is determined using specific criteria or linear interpolation. Equations are provided for calculating the competing sound level for a 50% correct (for example, if you answer 2 out of 3 or 3 out of 5 times on a test, you meet the criterion of "50% or more") speech recognition score based on the starting level and step size.

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 audiologic test battery and is a physiological measure that must be included in any comprehensive audiologic assessment. The purpose of tympanometry is to indirectly evaluate the function of middle ear by measuring aural acoustic admmittances with a probe to the ear cannel attached. This test can be evaluated with an aural acoustic immittance instrument, and in particular, the eardrum motility test and the acoustic reflex

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 optoacoustic 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 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.

Author Contributions

Conceptualization: Kyung-Ho Park, Young Jun Seo. Investigation: Michelle J. Suh. Methodology: Jihyun Lee, Wan-Ho Cho, In-Ki Jin. Project administration: Young Jun Seo. Resources: Jihyun Lee, Young Jun Seo. Supervision: Young Jun Seo. Writing—original draft: Michelle J. Suh, Young Jun Seo. Writing—review & editing: Wan-Ho Cho, In-Ki Jin, Tae Hoon Kong, Soo Hee Oh, Hyo-Jeong Lee, Seong Jun Choi, Dongchul Cha. Approval of final manuscript: all authors.

ORCID iDs

Michelle J. Suh	https://orcid.org/0000-0001-6345-7671
Jihyun Lee	https://orcid.org/0000-0003-0896-9062
Wan-Ho Cho	https://orcid.org/0000-0001-5606-6293
In-Ki Jin	https://orcid.org/0000-0002-0834-5981
Tae Hoon Kong	https://orcid.org/0000-0002-5612-5705
Soo Hee Oh	https://orcid.org/0000-0002-3745-1484
Hyo-Jeong Lee	https://orcid.org/0000-0003-2258-0803
Seong Jun Choi	https://orcid.org/0000-0003-4478-9704
Dongchul Cha	https://orcid.org/0000-0002-0043-5026
Kyung-Ho Park	https://orcid.org/0000-0003-1485-3250
Young Jun Seo	https://orcid.org/0000-0002-2839-4676

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