BRITISH STANDARD

BS EN 60645-5:2005

Electroacoustics — Audiometric equipment

Part 5: Instruments for the measurement of aural acoustic impedance/admittance

The European Standard EN 60645-5:2005 has the status of a British Standard

ICS 17.140.50

British Standards

National foreword

This British Standard is the official English language version of EN 60645-5:2005. It is identical with IEC 60645-5:2004. It supersedes BS EN 61027:1993, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EPL/29, Electro-acoustics, which has the responsibility to:

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English version

Electroacoustics – Audiometric equipment Part 5: Instruments for the measurement of aural acoustic impedance/admittance (IEC 60645-5:2004)

Electroacoustique –
Appareillage audiométrique
Partie 5: Instruments pour la mesure
de l'impédance ou de l'admittance aurale
(impédancemètres ou admittancemètres)
(CEI 60645-5:2004)

Akustik –
Audiometer
Teil 5: Geräte zur Messung der
akustischen Impedanzen/Admittanzen
des Gehörs
(IEC 60645-5:2004)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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CENELEC

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Foreword

The text of document 29/563/FDIS, future edition 1 of IEC 60645-5, prepared by IEC TC 29, Electroacoustics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60645-5 on 2004-12-01.

This European Standard supersedes EN 61027:1993.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2005-09-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2007-12-01

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60645-5:2004 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 389-1	NOTE	Harmonized as EN ISO 389-1:2000 (not modified).
ISO 389-2	NOTE	Harmonized as EN ISO 389-2:1996 (not modified).

CONTENTS

INTRODUCTION

Developments in the field of diagnostic hearing measurement have resulted in a number of instruments designed to evaluate the acoustic impedance/admittance of the human ear by means of acoustic probe signals having different frequencies and temporal characteristics. The practical use of such instruments concerns to a large extent the measurement of changes in acoustic impedance/admittance caused either by varying the air pressure in the external acoustic meatus or by activating the middle ear muscle reflex.

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 5: Instruments for the measurement of aural acoustic impedance/admittance

1 Scope

This part of IEC 60645 applies to 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. The standard is not intended to restrict development or incorporation of new features, nor to discourage innovative approaches.

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.

IEC 60126, *IEC reference coupler for the measurement of hearing aids using earphones coupled to the ear by means of ear inserts* [1]

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for safety*

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4, *Medical electrical equipment – Part 1: General requirements for safety – Collateral standard: Programmable electrical medical systems*

IEC 60645-1:2001, *Electroacoustics – Audiological equipment – Part 1: Pure-tone audiometers*

BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML, *Guide to the expression of uncertainty in measurement (GUM)*

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[1] To be revised as IEC 60318-5.

3 Terms and definitions

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

NOTE The units in this standard conform to the International System of Units (SI). However, for audiological measurements test results have traditionally often been reported in other units. To provide information on the conversion from such units to SI units, Annex B has been compiled.

3.1
aural impedance/admittance
general term covering all aspects of acoustic impedance/admittance of the ear

NOTE Throughout this standard the term aural impedance/admittance will be employed as a general term covering all aspects of acoustic impedance/admittance of the ear, except where reference is made to specific derivatives.

3.2
acoustic impedance
at a specified surface, quotient of sound pressure by volume velocity through the surface

NOTE 1 The symbol is Z_a and the unit is the pascal second per metre to the third power ($Pa \cdot s/m^3$)

NOTE 2 The quantity usually measured is the modulus.

3.3
acoustic resistance
real component of complex acoustic impedance

NOTE The symbol is R_a and the unit is the pascal second per metre to the third power ($Pa \cdot s/m^3$).

3.4
acoustic reactance
imaginary component of complex acoustic impedance

NOTE The symbol is X_a and the unit is the pascal second per metre to the third power ($Pa \cdot s/m^3$).

3.5
acoustic admittance
at a given surface, the reciprocal of acoustic impedance at the same surface

NOTE 1 The symbol is Y_a and the unit is the metre to the third power per pascal second ($m^3/Pa \cdot s$).

NOTE 2 Thus, the acoustic admittance at a given surface is the complex ratio of the volume velocity through the surface of the sound pressure averaged over the surface. The quantity usually measured is the modulus.

3.6
acoustic conductance
real component of complex acoustic admittance

NOTE The symbol is G_a and the unit is the metre to the third power per pascal second ($m^3/Pa \cdot s$).

3.7
acoustic susceptance
imaginary component of complex acoustic admittance

NOTE The symbol is B_a and the unit is the metre to the third power per pascal second ($m^3/Pa \cdot s$).

3.8
acoustic inertance
ratio of the driving sound pressure to the resulting rate of change in volume velocity

NOTE The symbol is M_a and the unit is the pascal second to the second power per metre to the third power ($Pa \cdot s^2/m^3$).

3.9
acoustic compliance
ratio of volume displacement to sound pressure

NOTE The symbol is C_a and the unit is the metre to third power per pascal (m^3/Pa).

3.10
equivalent volume
volume of an air-filled hard-walled cylindrical cavity that offers the equivalent acoustic impedance/admittance

NOTE 1 The volume is given by the formula:

$$V_e = \gamma \cdot p_s \cdot C_a = \rho \cdot c^2 \cdot C_a$$

where

V_e is the equivalent volume in m^3;

γ is the ratio of specific heat for air at constant pressure to that at constant volume (approximately 1,40);

p_s is the barometric air pressure in Pa;

ρ is the ambient density of air in kg/m^3, at the temperature and pressure of the measurement;

c is the speed of sound in m/s at the temperature and pressure of the measurement;

C_a is the acoustic compliance in m^3/Pa.

NOTE 2 It has been practice to refer to aural impedance/admittance at the probe tone frequency of 226 Hz as an equivalent volume of air.

NOTE 3 For a probe tone frequency of 226 Hz, the equivalent volume of air is equal to its physical volume provided the latter does not exceed 5 cm^3.

3.11
relative pressure in the external acoustic meatus
difference between the pressure in the external acoustic meatus and the ambient barometric pressure in daPa

3.12
probe
coupling device that is inserted into the external acoustic meatus to connect the instrument to the ear

3.13
ear tip
device used to provide a seal between the probe and the external acoustic meatus

3.14
probe signal
acoustic signal that is emitted into the external auditory meatus by means of a probe

NOTE The signal is used to measure acoustic impedance/admittance.

3.15
probe ear
ear into which the probe in inserted

3.16
measurement plane
plane located at the frontal surface of the probe perpendicular to the volume velocity vector

3.17
tympanometry
measurement of change of aural impedance/admittance as a function of air pressure in the external acoustic meatus

NOTE The measured acoustic impedance/admittance values may depend on rate and direction of change of air pressure as well as time spent with a certain constant air pressure in the external acoustic meatus.

3.17.1
measurement plane tympanometry
measurement of change of the aural impedance/admittance at the measurement plane, comprising the combined impedance/admittance of the middle ear and part of the external acoustic meatus

3.17.2
meatus-compensated tympanometry
measurement of the vector difference between the aural impedance/admittance obtained at the test pressure and that obtained at a specific reference pressure in the external acoustic meatus for a given fitting of the probe

NOTE 1 The reference pressure should be such as to effectively eliminate the influence of the middle ear.

NOTE 2 The reference pressure will normally be 200 daPa different from the indicated pressure, which gives maximum admittance or minimum impedance indication, or fixed at 200 daPa relative to ambient pressure.

3.18
tympanogram
graphical display of some quantity related to aural impedance/admittance as a function of air pressure in the external acoustic meatus

3.19
middle-ear muscle reflex
change in tonus of muscles of the middle ear in response to stimulation

NOTE The change may be measured as a variation in the acoustic impedance/admittance within the external auditory meatus

3.19.1
acoustic reflex
middle-ear muscle reflex elicited by an acoustic stimulus

3.19.2
non-acoustic reflex
middle-ear muscle reflex elicited by a non-acoustic stimulus

3.20
acoustic reflex activating stimulus
acoustic stimulus that is used to elicit an acoustic reflex

3.21
stimulus ear
ear to which a reflex activating stimulus is presented in order to elicit a middle ear muscle reflex

3.22
ipsilateral reflex
middle ear muscle reflex elicited in the stimulus ear

3.23
contralateral reflex
middle ear muscle reflex elicited in the ear contralateral to the stimulus ear

4 Requirements for specific instruments

Three different types of aural acoustic impedance/admittance instruments are specified by the requirements for minimum mandatory facilities (see Table 1). Other facilities are not precluded. The three types relate to their presumed primary application.

Table 1 – Mandatory functions for aural impedance/admittance instruments

	Type		
	1 Diagnostic/ clinical	**2** Tympanometry/ reflex screening	**3** Tympanometry screening
Probe signal frequency 226 Hz	x	x	x
Aural impedance/admittance measuring system			
Measurement plane tympanometry	x [a]	x [a]	x [a]
Meatus compensated tympanometry	x [a]	x [a]	x [a]
Pneumatic system			
Manual change of pressure	x		
Automatic change of pressure	x	x	x
Acoustic reflex activating system			
Contralateral routing	x		
Ipsilateral routing	x	x	
Acoustic stimuli:			
Pure tones	x	x	
Broad-band noise	x		
Stimulus level control	x		
Presentation of results			
Display or visual indicator	x	x	x
Printout	x		
Data interface	x		

[a] Indicating that either of the two alternatives shall be provided.

5 General specifications

5.1 Measuring system

5.1.1 Units of measurement

The instruments may be designated to measure one or more components of aural impedance/admittance. SI units or derived SI units shall be used. The units of measurement shall be indicated on the front panel of the instrument.

5.1.2 Probe signal

A probe signal in the form of a pure tone with a frequency of 226 Hz shall be provided in instruments of Types 1, 2 and 3. The actual frequency shall differ from its nominal frequency by less than ±1 % for Type 1 instruments and by less than ± 2 % for Types 2 and 3. The total harmonic distortion shall be less than 1 % for Type 1 and less than 3 % for Types 2 and 3, when measured as specified in Clause 6. If pure tones of frequencies other than 226 Hz are available, the same requirements with regard to frequency accuracy and harmonic distortion shall apply.

NOTE When tests such as multi-frequency tympanometry are performed which require frequency accuracy better than the 1 % specified, the manufacturer should state the accuracy of the frequency used for that test.

5.1.3 Probe signal level

For pure tones of any frequency, for stationary broadband and for non-stationary probe signals the level shall be such that the probability of activating the middle ear muscle reflex by the probe signal is acceptably small. For a 226 Hz pure tone probe signal, the sound pressure level shall be 90 dB or less as measured according to Clause 6.

NOTE This requires a level less than the mean value minus two standard deviations for the threshold level of the acoustic middle ear reflex in a sufficiently large otologically normal young adult population when the probe signal is used as a reflex activating stimulus. A population of 25 persons is considered to be sufficiently large. ISO 389-1 defines an "otologically normal person" as "a person in a normal state of health who is free from all signs or symptoms of ear disease and from obstructing wax in the ear canals and who has no history of undue exposure to noise, exposure to potentially ototoxic drugs or familial hearing loss".

5.1.4 Measurement range

For a 226 Hz probe tone the minimum ranges expressed as equivalent volume of air shall be: for measurement plane tympanometry, from 0,2 cm^3 to 5 cm^3; for meatus compensated tympanometry, from 0 cm^3 to 2 cm^3 in Types 1 and 2, and from 0 cm^3 to 1,2 cm^3 in Type 3 instruments.

The manufacturer shall state the sensitivity for the acoustic reflex measuring system and the stimulus level at which there is a possibility of artefactual change occurring in the measurement display synchronously with the presentation of the reflex eliciting stimulus.

NOTE Measurement of artefact on a hard-walled cavity does not necessarily represent the conditions that occur in human ears. Therefore no method of measurement of artefacts in human ears is specified.

5.1.5 Accuracy of measurement

The difference between indicated and actual impedance/admittance values shall not exceed ±5 % or ±0,1 cm^3 of the equivalent volume, or $\pm 10^{-9}$ m^3/Pa·s, whichever is greater. The manufacturer shall state the deviation between the static and the dynamic mode of operation and the method of measurement.

5.1.6 Temporal characteristics

The various temporal response parameters as defined in 10.1.6, measured in accordance with the procedure described in Annex C, shall not exceed 50 ms and overshoot and undershoot shall not exceed 10 %.

NOTE At probe tone frequencies higher than 226 Hz, shorter response times are desirable.

5.2 Pneumatic system

5.2.1 Pressure ranges

For instruments of Type 1, the range of relative pressure shall be at least from +200 daPa to –600 daPa.

For Types 2 and 3, the range shall be at least from +200 daPa to –200 daPa.

5.2.2 Maximum limits

The limits of relative pressure shall be –800 daPa and +600 daPa as measured in a 0,5 cm^3 cavity. These limits shall apply to all types of instruments. All instruments shall have a means which will prevent the pressure from suddenly reaching, or exceeding these limits.

5.2.3 Accuracy of the relative pressure indicator

For instruments of Type 1, the actual relative pressure produced by the instrument in cavities from 0,5 cm^3 to 5 cm^3 shall not differ from the indicated relative pressure by more than ± 10 daPa or ± 10 %, whichever is the greater.

For Types 2 and 3 instruments, the actual relative pressure produced in cavities from 0,5 cm^3 to 2 cm^3 shall not differ from the indicated relative pressure by more than ±10 daPa or ±15 %, whichever is greater.

These specifications shall be met for the rates of changes of pressure provided.

5.2.4 Rate of pressure change

Instruments of Type 1 shall at least provide the possibility of changing the relative pressure (increasing and/or decreasing) at a calibrated rate of 50 daPa/s ± 10 daPa/s, measured in cavities from 0,5 cm^3 to 5 cm^3.

NOTE Other rates may also be provided and specified by the manufacturer. This applies also to Types 2 and 3 instruments.

5.3 Acoustic reflex activating stimulus system

5.3.1 General requirements

Specifications for the acoustic reflex activating stimulus system are as given in Clauses 6, 8 and 10 of IEC 60645-1:2001, with the exceptions specified below.

NOTE If the instrument is designed to make hearing threshold measurements, the full text of IEC 60645-1 should apply.

5.3.2 Stimulus signals

5.3.2.1 Pure tone signals

When fixed frequencies are provided, they shall be selected from the standard audiometric frequencies. Type 1 instruments shall provide at least 500 Hz, 1 000 Hz, 2 000 Hz and 4 000 Hz stimuli for both contralateral and ipsilateral acoustic reflex stimulation and measurements; Type 2 instruments shall provide at least one of the frequencies 500 Hz, 1 000 Hz or 2 000 Hz stimuli for ipsilateral acoustic reflex stimulation and measurements. The frequency shall not deviate by more than ±1 % for Type 1 instruments and ±3 % for Type 2 instruments.

5.3.2.2 Pure tone harmonic distortion

For the frequencies and stimulus level settings listed in Table 2, the total harmonic distortion of the test tone shall not exceed 2,5 % for supra-aural earphones and 5 % for probe-type earphones for hearing levels up to 110 dB in the frequency range 500 Hz to 4 000 Hz. At higher level settings the maximum level of harmonics shall not exceed 5 % total harmonic distortion for supra-aural earphones, and 10 % total harmonic distortion for insert or probe-type earphones.

NOTE If the maximum output for an instrument corresponds to a hearing level of less than 110 dB, the requirement given should apply to the maximum output levels of the instruments.

5.3.2.3 Broad band noise

If a broad band (random) noise is provided, it shall have a spectrum pressure level, as measured acoustically, which is uniform within ±5 dB relative to the 1 000 Hz level over the frequency range of 500 Hz to 4 000 Hz for the supra-aural earphone, and within ±10 dB over the frequency range of 500 Hz to 4 000 Hz for the insert or probe-type earphone.

5.3.2.4 Other stimuli

If other types of stimuli are provided, the manufacturer shall describe the characteristics of such stimuli.

5.3.3 Stimulus level control

5.3.3.1 Markings

Instruments calibrated to this standard shall be identified either on the front panel or on the stimulus level control. The signal level control shall be identified by the designation "Hearing Level" (HL) or an equivalent national designation. The zero marking on the hearing level control shall correspond to an output from the transducer which relates to the reference equivalent values given in the relevant parts of ISO 389. If other transducers or other reference levels than those listed in the relevant parts of ISO 389 are used, the manufacturer shall state the origins and basis of the reference levels, together with the procedures and ear simulators or couplers to be used for calibration. The maximum level setting for each frequency and for the broad-band noise shall be indicated.

5.3.3.2 Intervals and minimum range

For instruments of Type 1, the stimulus level control shall cover at least the range listed in Table 2. Readings of stimulus level shall be indicated in intervals of 5 dB or less.

For instruments of Type 2, the stimulus level may be fixed and shall be specified by the manufacturer.

Table 2 – Minimum hearing level ranges for different stimuli for Type 1 instruments

Stimulus	500 Hz to 2 000 Hz	4 000 Hz	Noise
Hearing level range [a] for supra-aural earphones in dB	50 – 120	50 – 120	50 – 115
Hearing level range [a] for insert or probe-type earphones in dB	50 – 100	50 – 80	50 – 90
[a] In case of noise the range may alternatively be specified in terms of sound pressure levels.			

NOTE In children, stimulus levels in the ear canal may be higher than indicated on the stimulus level control.

5.3.3.3 Stimulus level control accuracy

The sound pressure level produced by the stimulus transducer shall not differ by more than ± 3 dB from the indicated values at any setting of the stimulus level control at indicated frequencies in the range of 500 Hz to 4 000 Hz and not by more than ±5 dB for noise stimuli, by supra-aural earphones; and by not more than ±5 dB over the frequency range from 500 Hz to 2 000 Hz and ${}^{+5}_{-10}$ dB at 4 000 Hz for insert or probe-type earphones.

5.3.4 Stimulus presentation control

5.3.4.1 General

Instruments shall be provided with a manual or automatic switch for presenting the stimulus signals. The switch and its associated circuit shall be such that the response is to the stimulus signal rather than to transients or to other noise.

5.3.4.2 On-off and signal-to-noise ratios

The on-off and signal-to-noise ratios shall be at least 70 dB. However, the A-weighted residual sound pressure level with the stimulus presentation switch in the off-position need not be less than 25 dB.

5.3.4.3 Rise-fall times

a) On-condition

When the stimulus presentation control is changed to the ON condition, the time taken for the sound pressure level produced by the transducer to attain –1 dB relative to its final steady state level shall not exceed 100 ms from the instant the stimulus presentation control is changed. The time required for the sound pressure level to rise in a progressive manner from –20 dB to –1 dB relative to its final steady state level shall not be less than 5 ms. At no time during the rise or decay of the tone shall the sound pressure level produced by the transducer attain a value exceeding 1 dB, relative to its steady state level in the ON position.

b) Off-condition

When the stimulus presentation control is changed to the OFF position the time taken for the sound pressure level produced by the transducer to fall to –20 dB relative to its steady state level in the ON position shall not exceed 100 ms from the instant the stimulus presentation control is changed. The time required for the sound pressure level to fall in a progressive manner from –1 dB to –20 dB relative to its steady state level in the ON position shall be not less than 5 ms.

5.3.4.4 Pulsed stimulus signal

If a pulsed stimulus signal is used, the manufacturer shall specify the temporal characteristics of the signal.

6 Demonstration of conformity with specifications

6.1 General

The following procedures are to be used for ensuring that the instruments meet the specifications given in this standard. Guidelines for routine calibration are described in Annex A.

6.2 Impedance/admittance measuring system

The probe shall be connected in turn to a set of hard-walled cavities, making an air-tight seal. The number, shapes and cavities shall be as specified in Clause 7. Tests shall be carried out at a probe frequency of 226 Hz.

The impedance/admittance indicator shall be read with the pressure set at ambient pressure and the test cavity corrected for temperature and barometric air pressure in accordance with the formula in 3.10.

NOTE For other types of probe signal the manufacturer should specify suitable test objects, which represent the extreme parts of the measurement range and at least one intermediate value.

6.3 Probe signal

6.3.1 Probe signal spectrum

The frequency of a pure tone probe signal shall be measured acoustically or electrically; the measuring instrument uncertainty shall be less than ±1 Hz or ±0,5 %, whichever is greater.

For probe signals other than pure tones, the probe signal spectrum shall be measured by applying the probe with air-tight seal on an acoustic coupler according to IEC 60126, with the ear tip placed according to the instructions provided by the manufacturer.

6.3.2 Probe signal level and harmonic distortion

The probe signal level and the harmonic distortion of the probe tone shall be measured by means of an acoustic coupler according to IEC 60126, to which the probe is coupled with an airtight seal, with the ear tip placed according to instructions (see 6.3.1).

6.4 Pneumatic system

6.4.1 Accuracy of air pressure indicator

The air pressure shall be checked by applying the probe with the air-tight seal to a pressure measuring system with a maximum measurement uncertainty of ±2 %, or ±3 daPa, whichever is greater, and a membrane volume displacement of less than 0,2 cm^3 for the range measured. At ambient pressure, the pressure measuring system shall have an air-filled volume of 0,5 cm^3 for the measurement of the maximum pressure limits required according to 5.2.2 and a volume of 5 cm^3 for the measurement of the minimum pressure limits according to 5.2.1.

NOTE 1 A membrane volume displacement of 0,2 cm^3 corresponds to the average volume change of the external auditory meatus during tympanometry.

NOTE 2 The small cavity volume of 0,5 cm^3 can be attained, for example, by using pressure transducers which can be partly filled with fluid (oil, water).

6.4.2 Rate of change of pressure

The rate of change of air pressure shall be measured by applying the probe with air-tight seal to a pressure measuring system with a maximum measurement uncertainty of ±2 % or ±3 daPa, whichever is greater, and a membrane volume displacement less than 0,2 cm^3.

The response of the measuring instrument shall be at least three times faster than the rate provided on the instrument to be tested.

Measurements shall be made with air-filled volumes of 0,5 cm^3 and 2 cm^3 coupled to the pressure measuring system.

6.4.3 Accuracy of air pressure indicator or analogue electrical output and/or recorder

The accuracy of the air pressure indicator or analogue electrical output and/or of the recorder according to 5.2.3 shall be checked by means of the same pressure measuring system as in 6.4.1 and 6.4.2. Measurements shall be made with air-filled volumes of 0,5 cm^3 and 2 cm^3 at the rates provided by the instrument tested.

6.5 Acoustic reflex activating stimulus signals

Measurements of harmonic distortion, stimulus level control accuracy and ON/OFF ratio of the supra-aural earphones shall be made on an acoustic coupler or an artificial ear as appropriate. For probe earphones, such measurements shall be made with the probe connected to an acoustic coupler (IEC 60126) with the probe tip placed according to instructions (see 6.3.1).

NOTE When calibration of ipsilateral stimuli is carried out on a 2 cm^3 coupler (IEC 60126), it must be noted that nominal levels (sound pressure level [SPL] and/or hearing level [HL] as indicated on the stimulus level control) may vary depending on the volume of the tested ear canal. The manufacturers should specify these variations for all pure tone frequencies provided and at least for 0,5 cm^3 and 1,0 cm^3 equivalent volume readings.

6.6 Maximum permitted expanded uncertainty of measurements

Table 3 specifies the maximum permitted expanded uncertainty for a probability of about 95 % equivalent to a coverage factor of k = 2, associated with the measurements undertaken in this standard, according to the ISO/IEC *Guide to the expression of uncertainty in measurement.* One set of values for U_{max} is given for basic type approval measurements.

The expanded uncertainties of measurements given in Table 3 are the maximum permitted for demonstration of conformance to the requirements of this International Standard. If the actual expanded uncertainty of a measurement performed by the test laboratory exceeds the maximum permitted value in Table 3, the measurement shall not be used to demonstrate conformance to the requirements of this standard.

Table 3 – Values of U_{max} for basic measurements

Measured quantity	Relevant subclause number	Basic $U_{max}(k = 2)$
Sound pressure level, 226 Hz to 4 000 Hz	5.1.3, 6.3.2, 10.1.4.2, 10.3.2	0,7 dB
Sound pressure level, broad band noise	5.3.2.3, 10.3.2	1,2 dB
Linearity of hearing level control	5.3.3.2, 5.3.3.3, 6.5, 10.3.2	0,1 dB
Frequency response	5.3.2.3	1,0 dB
Frequency	5.1.2, 6.3.1, 10.1.4.1, 10.3	0,2 % or 1 Hz
Total harmonic distortion	5.3.2.2, 6.3.2, 6.5, 10.3.1	0,5 %
Rise and fall time (ms)	5.3.4.3, 10.3.3	1 ms
Time constant	5.1.6, 10.1. 6	10 ms
Volume of air	5.1.4, 5.1.5, 7.2	0,2 cm^3
Aural impedance/admittance	5.1.5	1,5 %
Temperature	8.4.3, 10.1.1	0,5 °C
Relative humidity	8.5.3	5 %
Ambient pressure	10.1.1, 10.1.4.1, 10.2.1, 10.2.2	0,1 kPa
Air pressure	5.2.1, 5.2.2, 5.2.3, 6.4.1, 6.4.3	2 % or 3 daPa
Rate of air pressure change	5.2.4, 6.4.2	2 % or 3 daPa

7 Calibration cavities

7.1 General

For the purpose of calibrating the instruments for equivalent volume and for pressure, the manufacturer shall provide at least three calibration cavities for instruments of Type 1, and two calibration cavities for Types 2 and 3 instruments. This standard does not provide recommendations for calibration procedures for other components of acoustic impedance or admittance. The manufacturer shall specify the technique employed for calibrating such components.

7.2 Dimensions of calibration cavities

The calibration cavities shall be shaped as cylinders with a length/diameter ratio ranging between one and three. For Type 1, the three cavities shall have volumes of 0,5 cm^3, 2,0 cm^3 and 5,0 cm^3. For Types 2 and 3, the two cavities shall have volumes of 0,5 cm^3 and either 1,0 cm^3 or a volume near the maximum limit of the measurement range of the instrument. Additional cavities, when provided, shall have volumes from: 1,0 cm^3; 1,5 cm^3; 2,5 cm^3; 3,0 cm^3; 3,5 cm^3; 4,0 cm^3; 4,5 cm^3. Volume tolerances shall be ±2 % or 0,05 cm^3, whichever is greater.

7.3 Material of calibration cavity walls

The calibration cavities shall have hard, non-porous surfaces, preferably of metal or sufficiently hard and stable plastic.

7.4 Connection of probe to a calibration cavity

The cavities and the probe shall be designed in such a way that, when connected with an air-tight fit, the indicated volume of the cavity shall be obtained.

8 General requirements

8.1 Marking

The instrument shall be marked with the name of the manufacturer, the type as in Clause 4, the model and its serial number as well as the identification of the transducer(s) employed.

8.2 Instruction manual

An instruction manual shall be supplied with each instrument. In this manual the manufacturer shall specify all characteristics as required by this standard, with special reference to Clauses 5, 6 and 10 to ensure proper calibration of the instrument.

8.3 Safety requirements

8.3.1 General

Instruments shall conform to IEC safety requirements specified in IEC 60601-1 and IEC 60601-1-4.

8.3.2 Immunity to power and radio frequency fields

8.3.2.1 Instruments shall meet the requirements of IEC 60601-1-2 for electromagnetic compatibility (EMC).

8.3.2.2 During, and as a result of any EMC immunity testing, the following condition shall be met:

– under the EMC test conditions, the unwanted sound from any air conduction transducer shall not exceed a hearing level corresponding to 80 dB. Subclause 13.3 of IEC 60645-1:2001, gives methods for showing conformity.

8.4 Warm-up time

The maximum warm-up time shall be specified by the manufacturer and shall not exceed 10 min when the unit has been stored at room temperature. The performance requirements of this standard shall be met after the started warm-up time has elapsed and after any setting-up adjustments have been carried out in the manner prescribed by the manufacturer.

8.5 Supply variation and environmental conditions

8.5.1 Mains operation

The specifications shall be met when any long term deviation in any supply voltage or mains frequency in combination is least favourable within the limits of ±10 % supply voltage or ±5 % mains frequency. When any short term line variation occurs that affects the performance of the instrument, the instrument shall revert to a mode that will not endanger the subject under test.

8.5.2 Battery operation

The manufacturer shall state the limits of battery voltages within which the specification shall be met, and a suitable indicator shall be provided to ensure that the battery voltages are within the specified limits.

8.5.3 Temperature and humidity operating range

The specifications shall be met for all combinations of values of temperature within the range +15 °C to +35 °C and relative humidity within the range 30 % to 90 %, with the test cavity corrected for temperature and barometric air pressure as stated in 10.1.1.

8.6 Unwanted acoustic signals and radiation

8.6.1 Extraneous sound from probe

Extraneous sounds from any cause such as noise generated by the pneumatic system shall be such as not to affect the accuracy of measurements. This shall be verified using the 0,5 cm^3 test cavity under dynamic as well as static conditions.

8.6.2 Radiated acoustic noise

With the acoustic reflex activating stimulus OFF, the sound pressure level, frequency-weighted A and time-weighted S, of the noise radiated from the instrumentation including necessary recording devices provided by the manufacturer, when checked at a distance of 1 m from any part of the instrumentation, shall not exceed 50 dB during measurement.

9 Symbols, forms and formats for acoustic impedance/admittance data

9.1 Symbols for indicating measured quantities

Acoustic impedance:	Z_a
Acoustic resistance:	R_a
Acoustic reactance:	X_a
Acoustic admittance:	Y_a
Acoustic conductance:	G_a
Acoustic susceptance:	B_a
Acoustic compliance:	C_a
Relative pressure:	Δp_s
Equivalent volume:	V_e
Phase angle:	Φ_z, Φ_y

9.2 Tympanogram format

9.2.1 Horizontal axis

The horizontal axis shall indicate the relative pressure in daPa. The scale on this axis shall be linear. A scale value of 0 daPa shall represent atmospheric pressure.

9.2.2 Vertical axis

For admittance, conductance, susceptance or equivalent volume, the scale shall be linear. For impedance, resistance or reactance, a non-linear scale may be used and the direction of the scale in terms of increasing magnitude should be inverted relative to the linear scale.

9.2.3 Scale proportion

For a probe tone frequency of 226 Hz, the scale proportion should be such that 300 daPa on the relative pressure scale (horizontal axis) is equal to length to 1 cm^3 on the equivalent volume scale (vertical axis) or the corresponding value for the quantity of acoustic impedance. Additional scale proportions may be provided.

9.2.4 Probe ear

Provision shall be made for specifying into which ear the probe was inserted.

9.3 Acoustic reflex test format

9.3.1 Analogue or digital readout

The analogue or digital readout shall be calibrated in equivalent volume units or as specified in 5.1.1.

9.3.2 Recorder

9.3.2.1 The horizontal scale shall indicate time in seconds.

9.3.2.2 The vertical scale shall be calibrated in equivalent volume units or acoustic impedance/ admittance quantities as measured.

9.3.3 Stimulus ear

Provision shall be made for specifying into which ear the probe was inserted and to which ear the acoustic stimuli were applied (i.e. ipsilateral or contralateral).

9.4 Eustachian tube function test format

Since instruments may be used to obtain indications relating to the function of the Eustachian tube either in the presence of an intact tympanic membrane, or whether a membrane is perforated, for these tests the following format is recommended.

9.4.1 Horizontal axis

The horizontal axis shall indicate time in seconds.

9.4.2 Vertical axis

The vertical axis shall indicate air pressure in daPa. The scale on this axis shall be linear, with provision for both positive and negative pressures relative to atmospheric pressure.

NOTE Where printouts are available, their accuracy should meet the requirements of the standard.

10 Additional characteristics to be specified by the manufacturer

10.1 Aural impedance/admittance measurement system

10.1.1 Influence of ambient temperature and atmospheric pressure

The influence of ambient temperature and atmospheric pressure is a critical factor in impedance measurements. The manufacturer shall provide data to enable the user to obtain correct calibration with the appropriate test cavities as specified in Clause 7.

10.1.2 Probe dimensions

The manufacturer shall provide specific information regarding the dimensions of the probe and any associated tubing that might be used between the probe and the instrument.

NOTE It would be desirable to have probes of standardised features and dimensions; however, current research does not support any specific dimension requirements.

10.1.3 Maintenance information

The manufacturer shall provide data regarding the recommended procedures for cleaning, maintenance and replacement of the probe, ear tips, and any associated tubing. The manufacturer shall also advise as to how often these procedures need to be repeated.

10.1.4 Probe signal characteristics

10.1.4.1 Frequency

For instruments of Types 1 to 3 the probe signal frequency shall be 226 Hz. The manufacturer may supply any additional probe tone frequency provided that tolerances stated in 5.1.2 are met.

NOTE The acoustic admittance of an air-filled cavity of volume 1 cm^3 at standard atmospheric conditions (atmospheric pressure 101,3 kPa, temperature 20 °C) is 10^{-8} m^3/Pa·s at a frequency of 226 Hz.

10.1.4.2 Level

The manufacturer shall specify the sound pressure level for the probe signals as specified in 5.1.3, its tolerances and its variations as a function of loading volume as well as the conditions under which these measurements were made.

10.1.4.3 Non-stationary/pulsed probe signals

For probe signals other than the stationary, the manufacturer shall state the temporal and spectral characteristics of the probe signal. The manufacturer shall also specify the procedures to measure the temporal and spectral characteristics as well as their tolerances.

10.1.5 Acoustic impedance/admittance indicator

The manufacturer shall specify the SI units displayed, the ranges and their tolerances as well as their dependence on barometric pressure.

10.1.6 Temporal characteristics

For instruments which provide the measurement of temporal characteristics of the acoustic reflex, the initial latency, rise time, terminal latency, fall time and overshoot-undershoot are relevant to obtain correct measurements. These characteristics shall be stated by the manufacturer for the electrical output and any recording system for all types of impedance/admittance instruments. The manufacturer shall also provide tolerances for each of these characteristics using the procedures outlined in Annex C.

10.2 Pneumatic system

10.2.1 Pressure control system

The range of pressure variation relative to atmospheric (ambient) pressure shall be specified. When automatic change of pressure is provided, the rates of change shall also be specified.

10.2.2 Pressure indicator

The pressure in the external acoustic meatus shall be indicated by analogue or digital display. The accuracy of the display shall be specified as well as its limitations with regard to atmospheric pressure and altitude above sea level.

10.3 Acoustic reflex activating stimulus system

10.3.1 General

The manufacturer shall specify the types of stimulus signals provided.

For acoustic stimuli, the manufacturer shall specify the pure tone frequencies, with tolerances and maximum harmonic distortion, and the types of noises provided, their characteristics and tolerances.

For non-acoustic stimuli, the manufacturer shall specify the types of stimuli and describe their characteristics and tolerances.

10.3.2 Stimulus level control

The manufacturer shall specify the stimulus level control accuracy, range and intervals, as well as the maximum output levels for each of the acoustic signals provided, and any other pertinent characteristics.

10.3.3 Stimulus presentation control

For acoustic stimuli, an ON-OFF ratio, the rise and fall times, and the residual A-weighted sound pressure level in the OFF condition shall be specified by the manufacturer. If a pulsed signal is used, the manufacturer shall specify the temporal characteristics and their tolerances.

For non-acoustic stimuli, the manufacturer shall specify similarly the characteristics of the stimulus presentation control as applicable.

10.4 Analogue electrical output

10.4.1 Pneumatic system

When an analogue electrical output is provided, the output shall be linearly related to the relative pressure. The overall tolerances described in 5.2.3 shall be maintained when they are measured at the electrical output. The manufacturer shall specify the electric output and also specify any d.c. bias voltage, the type of circuit (single-ended or differential), the type of connector and the pin connections used. Minimum electrical load impedance for the specified sensitivity shall also be stated.

10.4.2 Acoustic reflex activating stimulus system

When an analogue electrical output is provided, it shall have a signal, which indicates the envelope of the reflex activating stimulus signal. The manufacturer shall specify the electric output.

10.4.3 Aural impedance/admittance measuring system

When an analogue electrical output signal is provided, the sensitivity shall be stated in voltage per unit of each quantity displayed. The manufacturer shall specify the electric output and also specify any d.c. bias voltage, the type of circuit (single-ended or differential), the type of connector and the pin connections used. Minimum electrical load impedance for the specified sensitivity shall also be stated. The temporal characteristics of the electrical output shall be specified as stated in 10.1.6, if relevant.

Annex A
(informative)

Routine calibration

A.1 General

The following parameters should be controlled at regular intervals:

A.2 Impedance/admittance indicator

Measure different volumes (see 6.2 and Clause 7).

A.3 Probe tone

Measure probe tone frequency and level (see 6.3).

A.4 Air pressure

Measure the air pressure range using a pressure measuring system (see 6.4).

A.5 Acoustic reflex activating stimulus signals

Measure ipsilateral and, if available, contralateral reflex signal levels (see 6.5), their frequencies (see 5.3.2.1) or spectral content (see 5.3.2.3 and 5.3.2.4) as appropriate and rise/fall times (see 5.3.4.3). For ipsilateral reflex an acoustic coupler, in accordance with IEC 60126, should be used according to ISO 389-2. For contralateral reflex ISO 389-1 or ISO 389-2 should be used, whichever is applicable to the earphone being calibrated.

Annex B
(informative)

Units and terms

B.1 Units used for aural impedance/admittance instruments

The units listed in this table have evolved by common practice in the health field and by analogy with electrical circuit elements.

NOTE It is the intent of the Working Group within IEC/TC 29 proposing standards on units and terminology to provide names for the units that will be the same for acoustic and/or mechanical systems. Reference should be made to appropriate IEC publications for preferred names.

Table B.1 – Symbols, units and conversion from c.g.s. to SI

Quantity	Symbol	SI units		Conversion c.g.s. → SI
		Units	Derived units used for measurements	
Acoustic impedance	Z_a	Pa·s/m³	10^{-9} Pa·s/mm³	1(acoust.)Ω = 1 dyn·s/cm⁵ = 10^5 Pa·s/m³
Acoustic resistance	R_a			
Acoustic reactance	X_a			
Impedance phase angle	Φ_Z	rad	$1° = \frac{2\pi}{360}$ rad	$1° = \frac{\pi}{180}$ rad
Acoustic admittance	Y_a	m^3/(Pa·s)	10^9 mm^3/(Pa·s)	1 (acoust.)mho = 1 cm^5/(dyn·s) = 10^{-5} m^3/(Pa·s)
Acoustic conductance	G_a			
Acoustic susceptance	B_a			
Admittance phase angle	Φ_Y	rad	$1° = \frac{2\pi}{360}$ rad	$1° = \frac{\pi}{180}$ rad
Acoustic inertance	M_a	Pa·s^2/m^3	Not applicable	1 dyn·s^2/cm^5 = 10^5 Pa·s^2/m^3
Acoustic compliance (capacitance)	C_a	m^3/Pa	Not applicable	1 cm^5/dyn = 10^{-5} m^3/Pa
Equivalent volume	V_e	m^3	1 cm^3 = 10^{-6} m^3	1 cm^3 = 10^{-6} m^3
Relative pressure	Δp_s	Pa	1 daPa = 10 Pa	1 mm H_2O = 0,98 daPa

B.2 Recommended terms and definitions

The following terms and definitions are recommended for aural impedance/admittance characteristics measured under various conditions.

B.2.1
static aural impedance/admittance
aural impedance/admittance observed at a constant specified air pressure and with a constant tonus of the middle ear muscles

B.2.2
dynamic aural impedance/admittance
aural impedance/admittance as observed with a continuous change in air pressure (i.e. by tympanometry) and/or during the activation of the middle ear muscle(s)

B.2.3
ambient aural impedance/admittance
aural impedance/admittance obtained with ambient air pressure in the external acoustic meatus, under either constant pressure or dynamic conditions

B.2.4
peak aural impedance/admittance
aural impedance/admittance obtained at a specific air pressure in the external acoustic meatus yielding an extremum in the measured acoustic impedance/admittance, under either constant pressure or dynamic conditions

B.2.5
reflex activated aural impedance/admittance
aural impedance/admittance measured with the middle ear muscle reflex activated by a defined stimulus at a specified air pressure in the external acoustic meatus

Annex C
(informative)

Overall temporal characteristics

For measuring the overall temporal characteristics as illustrated in Figure C.1, the probe should be connected to a hard-walled test cavity of 2 cm^3. A miniature sound source, fed by an electrical signal derived from the probe signal should be connected to the cavity near to the probe. By means of suitable switching circuits, the sound source should be activated to a level which corresponds to a decrease in test cavity volume of 0,2 cm^3. The response times according to Figure C.1 should be measured by the presentation of such simulated changes in equivalent volume with a 5 ms rise and fall-time and a duration of at least 1 s. The electrical output to be tested should be loaded by the specified minimum load impedance and connected to one channel of a two channel oscilloscope or Y-T recorder with upper frequency limit of at least 20 Hz (–3 dB).

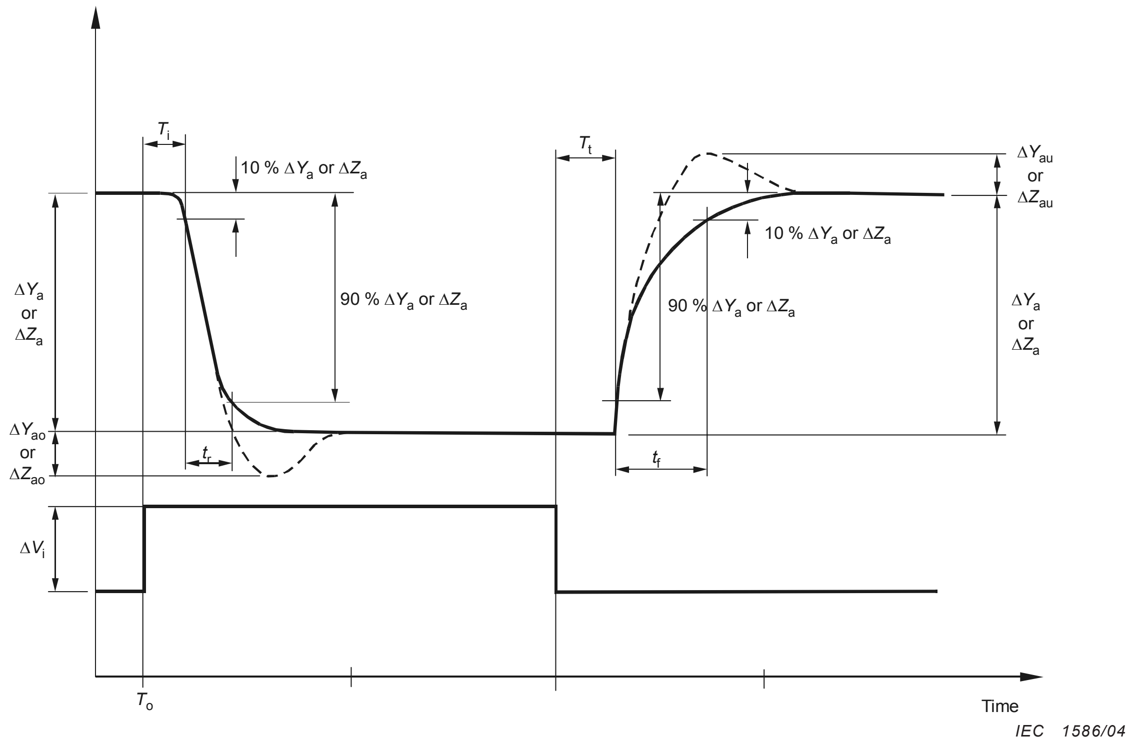

Figure C.1 – Overall temporal characteristics measured in a test cavity in response to step-wise input changes, starting at T_o

In Figure C.1, the dotted lines indicate overshoot and undershoot, to be expressed as a percentage by:

$$\frac{\Delta Y_{ao}}{\Delta Y_a} \cdot 100 \text{ or } \frac{\Delta Z_{ao}}{\Delta Z_a} \cdot 100 \text{ and } \frac{\Delta Y_{au}}{\Delta Y_a} \cdot 100 \text{ or } \frac{\Delta Z_{au}}{\Delta Z_a} \cdot 100$$

T_i	Initial latency: defined as the time in seconds from the stepwise beginning of the simulated input impedance/admittance change to 10 % of the measured steady-state impedance change.
t_r	Rise time: defined as the time in seconds from 10 % to 90 % of the measured steady-state impedance/admittance change.
T_t	Terminal latency: defined as the time in seconds from stepwise termination of the simulated input impedance/admittance change to 90 % of the measured steady-state impedance change.
t_f	Fall time: defined as the time in seconds from 90 % to 10 % of the measured steady-state impedance/admittance change after termination of the initial impedance change.
ΔV_i	Simulated stepwise change in input impedance/admittance.
ΔZ_a, ΔY_a	Change in steady-state value of impedance/admittance when the simulated change in input is switched on or off.
ΔZ_{ao}, ΔY_{ao}	Overshoot, the transient artefactual response in measured value prior to reaching steady-state when the simulated change in input is switched on.
ΔZ_{au}, ΔY_{au}	Undershoot, the transient artefactual response in measured value prior to reaching steady-state when the simulated change in input is switched off.

Overshoot and undershoot should be expressed in terms of percentage of change in indicated steady-state value, as shown in Figure C.1.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60126	- [1)]	IEC reference coupler for the measurement of hearing aids using earphones coupled to the ear by means of ear inserts	HD 305 S1	1977 [2)]
IEC 60601-1	- [1)]	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990 [2)]
IEC 60601-1-2	- [1)]	Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2001 [2)]
IEC 60601-1-4	- [1)]	Medical electrical equipment Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996 [2)]
IEC 60645-1	2001	Electroacoustics - Audiological equipment Part 1: Pure-tone audiometers	EN 60645-1	2001
BIPM/IEC/IFCC/ ISO/IUPAP/OIML	- [1)]	Guide to the expression of uncertainty in measurement (GUM)	-	-

[1)] Undated reference.

[2)] Valid edition at date of issue.

Bibliography

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

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