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Specification for

Audiometers

Spécification pour les audiomètres

Spezifikation für Gehörmesser

National foreword

This British Standard was prepared under the direction of the Electronics Equipment Standards Committee and is identical with IEC Publication 645 'Audiometers' published in 1979 by the International Electrotechnical Commission (IEC). This standard supersedes BS 2980 : 1958, which is therefore withdrawn.

Terminology and conventions. The text of the international standard has been approved as suitable for publication, without deviation, as a British Standard. Some terminology and certain conventions are not identical with those used in British Standards.

Cross-references

International standard	Corresponding British Standard
IEC 268-3 : 1969	BS 5428 Methods for specifying and measuring the characteristics of sound system equipment Part 2 : 1979 Amplifiers (Technically equivalent)
IEC 303 : 1970	BS 4668 : 1971 An acoustic coupler (IEC reference type) for the calibration of earphones used in audiometry (Technically equivalent)
IEC 318 : 1970	BS 4669 : 1971 An artificial ear of the wide band type for the calibration of earphones used in audiometry (Technically equivalent)
IEC 373 : 1971	BS 4009 : 1975 An artificial mastoid for the calibration of bone vibrators used in hearing aids and audiometers (Technically equivalent)
IEC 601-1 : 1977	BS 5724 Specification for safety of medical electrical equipment Part 1 : 1979 General requirements (Technically equivalent)

The technical committee has reviewed the provisions of ISO 389-1979 and has decided that they are acceptable for use in conjunction with this standard. The related British Standard is BS 2497 'Reference for the calibration of pure-tone audiometers'.

NOTE 1. In the note to 7.1 the relevant ISO standard to which reference is made is ISO 389.

NOTE 2. With reference to the footnote to 3.6 it should be noted that BS 2497 gives the values of reference equivalent threshold vibration levels for bone conduction.

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British Standard Specification for Audiometers

1. Scope

This standard specifies requirements for audiometers designed primarily for use in determining hearing threshold levels in comparison with a chosen standard reference threshold level *.

2. Object

The purpose of this standard is to ensure:

- a) that tests of hearing, particularly threshold, on a given human ear performed with different audiometers which comply with this standard shall give substantially the same results under comparable conditions;
- b) that the results obtained shall represent a good comparison between the hearing of the ear tested and the reference threshold of hearing.

Audiometers can be classified in the following ways: according to the type of test signal they generate (i.e. pure tone or speech or both), according to the mode of operation or according to their complexity or the range of auditory functions they test (i.e. diagnostic, screening, etc.). However, in order to rationalize the classification of audiometers, five types are defined. Audiometers with which it is possible to make a diagnostic assessment (i.e. having as a minimum both air and bone conduction facilities) are classified as Types 1, 2 and 3. Instruments with air conduction facilities only are classified as Types 4 and 5.

All audiometers and other equipment for subjective audiological tests can be considered as a series of functional units. This standard covers the general requirements for audiometers as a whole as well as their functional units: signal sources, signal level controls and transducers.

In addition, since the units specified cover the majority of audiometric applications, instruments which may not necessarily be conventional pure tone audiometers (such as an acoustic impedance-admittance system or a narrow-band noise generator) but which contain circuitry for measurement of auditory sensitivity or presentation of supraliminal signals shall, where possible, conform to the appropriate clauses of this standard. By using Table I, the reader should be able to find the appropriate clauses (5 to 9) of this standard which describe the performance requirements for a given instrument.

This standard is in no sense intended to restrict or inhibit the development and incorporation of new features or other improvements likely to assist with audiological measurement, especially instruments designed to test hearing by objective methods.

* Procedures for this purpose are under consideration by ISO.

TABLE I
General requirements

Characteristics	Signal sources	Signal level control	Transducers
5.1 Safety	6.1 Pure tones	7.1 Marking	9.1 Air conduction
5.2 Warm-up time	6.2 Speech	7.2 Accuracy of sound pressure and vibration levels	9.2 Bone conduction
5.3 Supply variation and environmental conditions	6.3 Masking sounds	7.4 Hearing level control	
5.4 Unwanted acoustic radiation		7.5 Masking sound	
		7.6 Tone switching	

3. Explanation of terms

For the purpose of this standard the following terms apply:

3.1 *Pure tone audiometer*

An instrument for the measurement of hearing for pure tones and in particular the auditory threshold.

3.1.1 *Manual audiometer*

A pure tone audiometer in which the signal presentations, frequency and hearing level selection and recording of the results are performed manually.

3.1.2 *Automatic recording audiometer*

A pure tone audiometer in which signal presentations, hearing level variation, frequency selection or frequency variation, and recording of subject responses are implemented automatically.

3.2 *Speech audiometer*

An instrument for the measurement of hearing for speech test material.

3.3 *Air conduction*

Transmission of sound through the external and middle ear to the internal ear.

3.4 *Bone conduction*

Transmission of sound to the internal ear mediated by mechanical vibration of the cranial bones and soft tissues.

3.5 *Equivalent threshold level (monaural listening)*

The equivalent threshold level of an ear at a specified frequency, for a specified type of transducer and for a stated force of application of the transducer to the human head is the vibration level or sound pressure level set up by the transducer at that frequency in a specified coupler or artificial ear when the transducer is actuated by that voltage which, with the transducer applied to the ear concerned, would correspond with the threshold of hearing.

3.6 *Reference equivalent threshold level **

The reference equivalent threshold level at a specified frequency, for a specified type of transducer, and for a specified pattern of coupler or artificial ear, is the modal value, at that frequency, of the equivalent threshold levels of an adequately large number of ears of otologically normal subjects within the inclusive age limits 18 to 30 years.

Note. — The values of reference equivalent threshold sound pressure levels for air conduction are specified in ISO Standard 389.

3.7 *Hearing level for pure tones*

The hearing level of a pure tone at a specified frequency, for a specific type of transducer and for a specified manner of application, is the vibration level or the sound pressure level of this signal set up by the transducer in a specified coupler or artificial ear minus the appropriate reference equivalent threshold level for bone or air conduction as applicable.

3.8 *Hearing threshold level for pure tones*

The hearing threshold level of a given ear at a specified frequency is the threshold level at that frequency expressed as hearing level.

3.9 *Artificial ear*

Device for the calibration of an earphone which presents to the earphone an acoustic impedance equivalent to the impedance presented by the average human ear. It is equipped with a calibrated microphone for the measurement of the sound pressure developed by the earphone.

Note. — An artificial ear is specified in IEC Publication 318, An IEC Artificial Ear, of the Wide Band Type, for the Calibration of Earphones Used in Audiometry.

3.10 *Acoustic coupler*

Cavity of predetermined shape and volume which is used for the calibration of an earphone in conjunction with a calibrated microphone to measure the sound pressure developed within the cavity.

Note. — An acoustic coupler is specified in IEC Publication 303, IEC Provisional Reference Coupler for the Calibration of Earphones Used in Audiometry.

3.11 *Mechanical coupler*

Device for calibration of a bone vibrator which presents to the bone vibrator a specified mechanical impedance. It is equipped with a transducer suitable for the measurement of vibromotive force or acceleration.

Note. — A mechanical coupler is specified in IEC Publication 373, An IEC Mechanical Coupler for the Calibration of Bone Vibrators Having a Specified Contact Area and Being Applied with a Specified Static Force.

3.12 *Masking*

Process by which the threshold of audibility of a sound is raised by the presence of another sound.

3.13 *Otologically normal subject*

For the purpose of this standard an otologically normal subject is understood to be a person in a normal state of health who is free from all signs or symptoms of ear disease and from wax in the ear canal and has no history of undue exposure to noise.

* The values of reference equivalent threshold vibration levels for bone conduction are under consideration by ISO.

4. Recommendations for specific types of audiometers

The minimum mandatory facilities required for each type of audiometer are given in Table II. Other facilities are not precluded and those which are particularly recommended are included in the table. Optional facilities, however, are not specified in detail in this standard.

TABLE II
Facilities of various types of audiometers

Capability	Type 1	Type 2	Type 3	Type 4	Type 5
Air conduction	×	×	×	×	×
Two earphones	×	×	×	×	
Bone conduction	×	×	×		
<i>Masking (pure tones)</i>					
1. Narrow-band noise	×	×			
2. Narrow-band noise or other	×	×	×		
3. Broad-band noise	×	×			
<i>Masking (speech)</i>	o	×			
<i>Routing of masking</i>					
Contralateral earphone	×	×	×		
Ipsilateral earphone	×	×			
Bone vibrator	×	o			
<i>Reference tone</i>					
Alternate	×	×			
Simultaneous	×				
Alternate, monaural, bi-frequency	o				
<i>Patient's response</i>					
Signal system	×	×	×	×	
Auxiliary output (e.g. loudspeaker)	×	o	o		
Input for external signal source (e.g. speech)	×	×	o		
Hearing level and frequency range	See Table III				
<i>Frequency control</i>					
1. Fixed frequencies	×	×	×	×	×
2. Continuously variable frequency	o				
<i>Tone presentation</i>					
1. Continuous tone	×	×	×	×	×
2. Automatic pulsed tone	×	×		×	
Test signal indicating device	×	×			
Audible monitoring of test signal	o	o			
Operator to subject speech communication	o	o			
Noise-reducing earphones				o	o

× : Mandatory minimum requirement

o : Desirable additional facility

1) If an input for external speech source is provided, speech weighted random noise (see Sub-clause 6.3.2c)) may be used as an alternative

2) Only required for use with an external speech source. In this case, the masking sound may be either broad-band or speech weighted random noise

3) For automatic recording audiometers this feature is not required

4) For manual audiometers this feature is not required.

5. General requirements

5.1 Safety requirements

Mains (power-line) operated instruments shall conform to minimum IEC safety requirements (see IEC Publication 601-1, Safety of Medical Electrical Equipment. Part 1 : General Requirements).

5.2 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 stated warm-up time has elapsed and after any setting-up adjustments have been carried out in the manner prescribed by the manufacturer.

5.3 Supply variation and environmental conditions

5.3.1 Mains operation

The specifications shall be met when any deviation in supply voltage or mains frequency in combination is least favourable within the limits of $\pm 10\%$ supply voltage and $\pm 5\%$ mains frequency.

5.3.2 Battery operation

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

5.3.3 Temperature and humidity operating range

The specifications shall be met for all combinations of values of temperature within the range $+15\text{ }^{\circ}\text{C}$ to $+35\text{ }^{\circ}\text{C}$ and relative humidity within the range 30% to 90%.

5.3.4 Conformity with each of the specifications in Sub-clauses 5.3.1, 5.3.2 and 5.3.3 may be demonstrated, with one earphone, by measuring frequency, distortion and sound pressure level at 1 000 Hz indicated frequency at a hearing level of 100 dB or at the maximum hearing level setting, whichever is lower. Distortion measurements shall be made as indicated in Sub-clause 6.1.4.

Notes 1. — For the test specified in Sub-clause 5.3.3, the earphone may be temporarily removed from the test environment.

2. — If 1 000 Hz is not provided on a Type 5 instrument, the nearest frequency should be used.

5.4 Unwanted acoustic radiation

5.4.1 General

Objective acoustical measurements may be impracticable for testing certain characteristics of audiometer performance. In such cases, subjective tests (e.g. as described in Appendix A) shall be performed using a test crew consisting of an adequate number of selected otologically normal subjects whose hearing threshold levels shall not exceed 10 dB for the test frequencies 250 Hz to 4 000 Hz and not exceed 20 dB for the frequencies 125 Hz, 6 000 Hz and 8 000 Hz.