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INTERNATIONAL RECOMMENDATION

Pure-tone audiometers

Audiomètres à sons purs

OIML R 104

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FOREWORD

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PURE-TONE AUDIOMETERS

1 Scope

This Recommendation deals with pure-tone audiometers designed for use in determining hearing threshold levels by comparison with the standard reference threshold levels by means of psychoacoustic test methods. The Recommendation is consistent with the requirements of the IEC Publication 645-1, "Audiometers - Part 1: Pure-tone audiometers", first edition 1992. It contains an appropriate test scheme for pattern evaluation and for verification.

2 Construction and maximum permissible errors

2.1 Pure-tone audiometers that are submitted to the control of Legal Metrology Services shall comply with the requirements of Publication 645-1 of the International Electrotechnical Commission, first edition 1992, in which pure-tone audiometers having various minimum mandatory facilities are referred to as types 1 to 5. The errors of pure-tone audiometers shall be within the maximum errors that are specified in that Publication, and which are to be considered as the maximum permissible errors on initial and subsequent verification.

In a multi-function instrument (e.g. a pure-tone audiometer having facilities for speech audiometry) the requirements of this Recommendation refer only to the parts of the instrument related to pure-tone audiometry.

Note: A Standard for speech audiometric equipment, which will form Part 2 of IEC Publication 645, is under preparation by IEC Technical Committee 29.

- 2.2 Pure-tone audiometers shall be tested using acoustic and mechanical couplers made according to the following IEC Publications:
 - IEC 126, "IEC reference coupler for the measurement of hearing aids using earphones coupled to the ear by means of ear inserts", second edition 1973
 - IEC 303, "IEC provisional reference coupler for the calibration of earphones used in audiometry", first edition 1970
 - IEC 318, "An IEC artificial ear, of the wide band type, for the calibration of earphones used in audiometry", first edition 1970
 - IEC 373, "Mechanical coupler for measurements on bone vibrators", second edition 1990
 - IEC 711, "Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts", first edition 1981

- 2.3 Pure-tone audiometers shall be calibrated in accordance with the relevant parts of the following ISO Standards:
 - ISO 389, "Acoustics Standard reference zero for the calibration of pure-tone air conduction audiometers ", third edition 1991
 - Notes: 1) Reference equivalent threshold sound-pressure levels in a coupler in accordance with IEC Publication 303 and in an artificial ear in accordance with IEC Publication 318 are given in Annex A.
 - 2) Supplementary data applicable to insert earphones of specified patterns used in conjunction with a coupler in accordance with IEC Publication 126, or an occluded-ear simulator in accordance with IEC Publication 711, are specified in Draft Amendment ISO 389: 1985/DAM 1, dated 1991.08.01.
 - ISO 7566, "Acoustics Standard reference zero for the calibration of pure-tone bone-conduction audiometers", first edition 1987

Note: Reference equivalent threshold force levels on a mechanical coupler in accordance with IEC 373 are given in Annex B.

 ISO 8798, "Acoustics - Reference levels for narrow band masking noise", first edition 1987

Note: Reference levels of masking noise with bandwidths from one-third octave to one-half octave are given in Annex C.

- 2.4 When different values for maximum permissible errors in service and at verification are prescribed by national regulations, the maximum permissible errors in service shall be 1.25 times the values prescribed for verification.
- 2.5 The programming and operation of computer-controlled audiometers shall be such that the test results are consistent with those obtained with manual or automatic recording audiometers, using the methods described in ISO 8253-1, "Acoustics Audiometric test methods Part 1: Basic pure-tone air and bone conduction threshold audiometry", first edition 1989.
- 2.6 For audiogram forms provided as an integral part of an audiometer, one octave on the frequency axis shall have the same length of scale as 20 dB on the hearing-level axis.

Note: For audiograms displayed on a screen, this requirement may be only approximately achievable.

2.7 The characteristics to be examined for pattern evaluation and for verification are listed in Annex D.

3 Stability

The materials used and the construction of a pure-tone audiometer, including the associated earphones and bone vibrator, shall ensure sufficient stability so that the instrument's errors do not exceed the maximum permissible errors specified in clause 2 when it is set up in accordance with the manufacturer's instructions for normal use.

4 Inscriptions and markings

- 4.1 Pure-tone audiometers shall bear, clearly and indelibly, the following markings:
 - manufacturer's trade mark
 - pattern designation
 - type
 - serial number
 - pattern-approval sign in conformity with national regulations
- 4.2 The earphones and bone vibrator shall be unambiguously identifiable as associated with the main instrument.
- 4.3 Every pure-tone audiometer shall be accompanied by an instruction manual which shall include the information listed in subclause 10.2 of IEC Publication 645-1.

The instruction manual shall additionally recommend that the user personally perform routine checks and subjective tests on the equipment in use to ensure as far as possible that the equipment is working correctly and that its calibration has not been noticeably altered. An example of procedures for such checking is given in Annex E. A suitable checklist for these tests shall be provided with the instruction manual, which shall state that these checks should be performed regularly. Equipment that is used daily should be checked at least weekly. Equipment that is used only occasionally should be checked before each use.

5 Marks

It shall be possible to protect, by means of seals or marks, the parts and components of pure-tone audiometers that are accessible to the user and that may influence the instruments' performance characteristics.

A suitable place for the application of verification marks shall be provided.

ANNEX A (mandatory)

REFERENCE EQUIVALENT THRESHOLD SOUND-PRESSURE LEVELS according to ISO 389

The reference equivalent threshold sound-pressure levels (RETSPL) are dependent on the pattern of earphone and on the pattern of acoustic coupler used to calibrate it.

A.1 Beyer DT 48 and Telephonics TDH 39 earphones

The RETSPL values for two different earphones in a coupler in accordance with IEC Publication 303 are given in Table A.1.

The Beyer DT 48 earphone shall be used with a flat cushion when placed on a human ear, but the cushion shall be replaced by an adapter when placed on the coupler as specified in Mrass, H. and Diestel, H.G., Acustica 9 (1959), pp. 61-64. The TDH 39 earphone shall be used with an MX 41/AR (or model 51) cushion on both the human ear and the coupler.

The earphone shall be applied to the coupler without acoustic leakage with a nominal static force of 4.5 N \pm 0.5 N, not including the weight of the earphone itself.

Table A.1
Recommended reference equivalent threshold sound-pressure levels (RETSPL) in a coupler in accordance with IEC Publication 303 (rounded to the nearest half decibel)

Pattern of earphone:	Beyer DT 48	Telephonics TDH 39	
Frequency	RETSPL (reference: 20 μPa)		
Hz		dB	
125	47.5	45.0	
160	40.5	37.5	
200	34.0	31.5	
250	28.5	25.5	
315	23.0	20.0	
400	18.5	15.0	
500	14.5	11.5	
630	11.5	8.5	
750	9.5	7.5	
800	9.0	7.0	
1 000	8.0	7.0	
1 250	7.5	6.5	
1 500	7.5	6.5	
1 600	7.5	7.0	
2 000	8.0	9.0	
2 500	7.0	9.5	
3 000	6.0	10.0	
3 150	6.0	10.0	
4 000	5.5	9.5	
5 000	7.0	13.0	
6 000	8.0	15.5	
6 300	9.0	15.0	
8 000	14.5	13.0	

A.2 Other supra-aural earphones

The RETSPL values for supra-aural earphones in an artificial ear in accordance with IEC Publication 318 are given in Table A.2. These values are applicable to earphones meeting the requirements of IEC 645-1, subclause 9.1.1. However, patterns of earphones specified in A.1 are excluded in order to avoid uncertainties that might otherwise arise.

The RETSPL values apply when the earphone is coupled to the artificial ear under the following conditions:

- a) The earphone and artificial ear are coaxial and the axis is vertical.
- b) There is no acoustic leakage.
- c) The coupling is made with a nominal static force of 4.5 N \pm 0.5 N, not including the weight of the earphone.

Table A.2
Reference equivalent threshold sound-pressure levels (RETSPL) in an artificial ear conforming to IEC Publication 318

	8
Frequency	RETSPL (reference: 20 μPa)
Hz	dB
125	45.0
160	38.5
200	32.5
250	27.0
315	22.0
400	17.0
500	13.5
630	10.5
750	9.0
800	8.5
1 000	7.5
1 250	7.5
1 500	7.5
1 600	8.0
2 000	9.0
2 500	10.5
3 000	11.5
3 150	11.5
4 000	12.0
5 000	11.0
6 000	16.0
6 300	21.0
8 000	15.5

(rounded to the nearest half decibel)

ANNEX B (mandatory)

REFERENCE EQUIVALENT THRESHOLD FORCE LEVELS according to ISO 7566

- B.1 Reference equivalent threshold force levels (RETFL) for cases in which the vibrator is located on the mastoid bone are given in Table B.1. They apply when the following conditions are met:
 - a) The bone vibrator meets the requirements of IEC 645-1, subclauses 5.5.3 and 9.2.
 - Note: The data specified in Table B.1 are based on hearing threshold measurements with a limited number of bone vibrator models, especially at frequencies above 4 kHz (see the bibliographies included in ISO 7566, Annexes A and C).
 - b) The mechanical coupler complies with the specification in IEC 373, second edition 1990.
 - c) The bone vibrator is attached to the mechanical coupler with a static force of $5.4~\mathrm{N} \pm 0.5~\mathrm{N}.$
 - d) The bone vibrator and mechanical coupler are brought to the correct operating temperature of 23 $^{\circ}C$ \pm 1 $^{\circ}C$.

Note: Because of the high thermal capacity of the mechanical coupler, a period of several hours may be required to bring the system to thermal equilibrium before calibration. Deviation from this temperature may be allowed only if data for the temperature dependance of the performance of the specific type of bone vibrator on the mechanical coupler are available.

Table B.1
Reference equivalent threshold force levels (RETFL) when the vibrator is located on the mastoid bone

Frequency	RETFL (reference: 1 μN)
Hz	dB
250	67.0
315	64.0
400	61.0
500	58.0
630	52.5
750	48.5
800	47.0
1 000	42.5
1 250	39.0
1 500	36.5
1 600	35.5
2 000	31.0
2 500	29.5
3 000	30.0
3 150	31.0
4 000	35.5
5 000	40.0
6 000	40.0
6 300	40.0
8 000	40.0

B.2 Interim differences between reference equivalent threshold force levels according to whether the vibrator is located on the forehead or the mastoid are given in Table B.2. They apply when the conditions of B.1 are met.

Table B.2
Interim differences
between reference equivalent threshold force levels (RETFL)
for forehead and mastoid location of the vibrator

Frequency Hz	RETFL (forehead) minus RETFL (mastoid) dB
250	12.0
315	12.5
400	13.5
500	14.0
630	13.5
750	13.0
800	12.0
1 000	8.5
1 250	10.0
1 500	11.0
1 600	11.0
2 000	11.5
2 500	12.0
3 000	12.0
3 150	11.5
4 000	8.0
5 000	11.0
6 000	11.0
6 300	10.0
8 000	10.0

ANNEX C (mandatory)

REFERENCE LEVELS FOR NARROW-BAND MASKING NOISE according to ISO 8798

Reference levels for the calibration of narrow-band masking noise in pure-tone audiometers are specified in Table C.1. The data are given as levels to be added to the reference equivalent threshold sound-pressure levels for the corresponding pure-tone frequencies when the masking earphone is placed on the appropriate acoustic coupler or artificial ear. The reference levels are presented for noise bandwidths of one-third octave and one-half octave for preferred one-third octave and for additional intermediate audiometric frequencies. For any noise bandwidth between one-third octave and one-half octave, the reference level is the level derived by interpolation.

Table C.1
Reference levels for narrow-band masking noise

Centre	Reference levels for bandwidth		
frequency Hz	One-third octave	One-half octave B	
125	4	4	
160	4	4	
200	4	4	
250	4	4	
315	4	4	
400	4	5	
500	4	6	
630	5	6	
750	5	7	
800	5	7	
1 000	6	7	
1 250	6	8	
1 500	6	8	
1 600	6	8	
2 000	6	8	
2 500	6	8	
3 000	6	7	
3 150	6	7	
4 000	5	7	
5 000	5	7	
6 000	5	7	
6 300	5	6	
8 000	5	6	

ANNEX D (mandatory)

PROCEDURES FOR PATTERN EVALUATION AND VERIFICATION OF PURE-TONE AUDIOMETERS

The following test scheme specifies the procedures for pattern evaluation and for two stages of verification (stage 1: basic verification, stage 2: periodic verification). It is recommended that stage 2 procedures be performed on the equipment in its normal working situation.

Note: The scheme is in accordance with ISO 8253-1: "Acoustics -Audiometric test methods - Part 1: Basic pure-tone air and bone conduction threshold audiometry", first edition 1989.

D.1 Preferably five specimens of the same pattern should be submitted for pattern evaluation. If fewer than three specimens are tested, the acceptance for verification may be limited to two years so that further experience with the pattern may be gained.

The characteristics to be examined for pattern evaluation are listed in Table D.1, column 2.

D.2 Basic verification (stage 1, referred to as stage C in ISO 8253-1) shall be performed on audiometers before their delivery to the user; it need not be employed routinely but may be required when a serious equipment fault or error occurs or when, after a long period of time, it is suspected that the equipment may no longer be performing fully to specification. It may, however, be advisable to submit equipment for a stage 1 verification after, for example, five years of use if it has not otherwise been subject to a test during that time.

The characteristics to be examined for the basic verification are listed in Table D.1, column 3.

D.3 Periodic verification (stage 2, referred to as stage B in ISO 8253-1) should preferably be performed at intervals of three months, although other intervals between tests may be acceptable in the light of experience with particular equipment in known conditions of use. The maximum interval between such verifications, however, should not exceed twelve months.

The characteristics to be examined for periodic verifications are given in Table D.1, column 4.

Table D.1
Characteristics to be examined for pattern evaluation and for verification of pure-tone audiometers

Instrument characteristics	Pattern evaluation	Basic verification	Periodic verification
(relevant clauses of IEC 645-1 are given in brackets)		(stage 1)	(stage 2)
I. General characteristics			
1. Electrical safety (5.1)	X		
2. Subject's response system (5.2, 10.2 o)	X		
3. Warm-up time (5.3)	X		

Instrument characteristics	Pattern evaluation	Basic verification	Periodic verification
(relevant clauses of IEC 645-1		(stage 1)	(stage 2)
are given in brackets)		()	(stage 2)
4. Sensitivity to temperature and			
humidity (5.4.1, 5.4.4, 10.2 b)	X		
5. Supply voltage (5.4.2, 5.4.3,			
5.4.4, 10.2 b)	X		
6. Electrostatic and electromagnetic interference (5.4.5)	v		
	X		
7. Unwanted sound (5.5)	X	x (except 5.5.3)	
8. External signal input (6.2, 7.2)	X	(except 3.3.3)	
II. Pure-tone signal characteristics			
9. Frequency and hearing level range			
(6.1.1, 8.1, 8.2.1)	X		
10. Frequency accuracy (6.1.2, 8)	X	X	X
11. Harmonic distortion (6.1.3, 8)	X	X	X
12. Rate of frequency change (6.1.4)	X	X	
		ep-frequency	
	audi	ometers)	
13. Frequency modulation (6.1.5, 10.2 i)	X		
14. Level accuracy (7.3, 8.2.4)	X	X	X
15 Haaring laval control		(at select	ted levels)
15. Hearing-level control (7.4, 8.2.2, 8.2.4, 8.2.5)	X	X	
(1.1, 0.2.2, 0.2.1, 0.2.3)	A	(at selected	
		frequencies)	
16. Tone switching (7.6, 8)	X	X	
III. Masking-noise characteristics			
17. Level range (7.5.4)	v		
	X	v	
18. Frequency spectrum (6.3, 10.2 n)	X	X	
19. Level accuracy (7.5.2, 7.5.3)	X	X (at select	x ted levels)
20. Level control (7.5.3)	X	X	ed ievels)
-11.0.00000 (.10.0)	14	(at selected centre	e
		frequencies)	
IV. Transducers			
21. Earphones (9.1, 10.2 j)	X	X (bood bond	X I force only)
22. Bone vibrator (9.2, 10.2 d)	X	(nead band X	l force only)
22. Done violator (7.2, 10.2 a)	Λ		l force only)

It is recommended that, to some extent, routine checking and, especially, subjective listening tests should be included both in pattern evaluation and in each verification stage. A recommended procedure in accordance with ISO 8253-1, which may be partly or fully applied as appropriate, is given in Annex E.

ANNEX E

RECOMMENDED PROCEDURES FOR ROUTINE CHECKS AND SUBJECTIVE TESTS TO BE PERFORMED BY THE USER OF PURE-TONE AUDIOMETERS AND TO BE PARTLY OR FULLY INCLUDED IN PATTERN EVALUATION AND VERIFICATION TESTS AS APPROPRIATE

The recommended procedures for routine checks and subjective tests, referred to as stage A in ISO 8253-1, are all simple tests, not requiring the use of measuring instruments.

The most important elements are the subjective tests given in E.6 to E.9, and these tests can be successfully performed only by an operator with unimpaired and preferably very good hearing.

The ambient noise conditions during the tests should not be substantially worse than those encountered when the equipment is in use.

- Notes: 1) The checking procedures described in E.1 to E.9 should be carried out with the audiometer set up in its usual working situation. If a booth or separate test room is used, the equipment should be checked as installed; an assistant may be required in order to carry out the procedures. The checks shall then include the inter-connections between the audiometer and the equipment in the booth, but the additional connecting leads and any plug and socket connections at the junction box should be examined, as well as potential sources of intermittent or incorrect connection.
 - 2) When subjective checks of bone-conduction threshold levels are being performed by an operator with normal hearing, air-conducted sound radiated from the bone vibrator may be heard at a level high enough to invalidate this test, especially at frequencies above 2 000 Hz. A sufficient attenuation of this air-conducted sound may be achieved by wearing earplugs during the tests at frequencies of 2 000 Hz and above.
- E.1 Clean and examine the audiometer and all accessories. Check earphone cushions, plugs, main leads and accessory leads for signs of wear or damage. (Damaged or badly worn parts should be replaced.)
- E.2 Switch on the equipment and let it warm up for the time specified by the manufacturer. Adjust any settings as specified by the manufacturer. On battery-powered equipment, check the state of the battery by the specified method. Check that markings on the earphone and the bone vibrator correspond with the instrument's marking.
- E.3 Check that the subject's signal system operates correctly.
- E.4 Check, if appropriate, the subject's communication speech circuits, applying procedures similar to those used for pure-tone function.
- E.5 Check the tension of the headset headband and of the bone-vibrator headband. Ensure that swivel joints are free to return without being excessively slack. Check headbands and swivel joints on noise-excluding headsets for signs of wear, strain or metal fatigue.

- E.6 Check that the audiometer output is approximately correct on both air conduction and bone conduction by sweeping at a hearing level of, for example, 10 dB or 15 dB and listening for "just audible" tones. This test shall be performed at all appropriate frequencies and for both earphones, as well as for the bone vibrator.
- E.7 Check at a high level (for example hearing levels of 60 dB on air conduction and 40 dB on bone conduction) all appropriate functions (and both earphones) at all frequencies used; listen for correct function, absence of distortion, freedom from switch clicks, etc. Check all earphones (including masking transducers) and the bone vibrator for absence of distortion and absence of faulty connections; check plugs and leads for absence of faulty connections. Check that all switch knobs are secure and that lamps and indicators work correctly.
- E.8 Listen at low levels for any sign of noise or hum, for unwanted sounds (break-through arising when a signal is introduced in another channel) or for any change in tone quality when masking is introduced. Check that attenuators do attenuate the signals over their full range and that attenuators that are intended to be operated while a tone is being delivered are free from electrical or mechanical noise. Check that switch keys operate silently and that no noise emitted by the instrument is audible at the subject's position.
- E.9 On automatic recording audiometers, check the marking pen and the mechanical operation and function of limit switches and frequency switches. Check that no extraneous instrument noise is audible at the subject's position.