Australian Standard™

Electroacoustics—Audiological equipment

Part 1: Pure-tone audiometers (IEC 60645-1:2001, MOD)

Standards Australia

This Australian Standard was prepared by Committee AV-003, Acoustics Human Effects. It was approved on behalf of the Council of Standards Australia on 29 November 2002 and published on 20 December 2002.

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Association of Australian Acoustical Consultants

Association of Consulting Engineers Australia

Australian Acoustical Society

Australian Chamber of Commerce and Industry

Australian Hearing

Department of Consumer & Employment Protection, WorkSafe Division, W.A.

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee AV-003, Acoustics Human Effects to be used as a means to demonstrate compliance with the relevant essential principles in new medical device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is an adoption with national modifications and has been reproduced from IEC 60645-1:2001, *Electroacoustics—Audiological equipment*, Part 1: *Pure-tone audiometers*.

Variations to the IEC text for application in Australia are listed below and the affected text is indicated by a marginal bar.

Committee AV-003 considered that particular sound levels set in IEC 60645-1 were insufficient to demonstrate conformity.

As this Standard is reproduced from an International Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text ‘this part of IEC 60645’ should read ‘this Australian Standard’.

(c) A full point substitutes for a comma when referring to a decimal marker.

(d) In Clause 13.6.1, *delete* the existing text ‘70 dB’, and *replace* with ‘80 dB’. *Delete* the existing text ‘30 dB or the maximum, which is lower’, and *replace* with ‘30 dB or at a level sufficient to demonstrate conformity’.

(e) In Clause 13.7.2, *delete* the existing text ‘70 dB’ and *replace* with ‘80 dB’.

The objective of this Standard is to specify general requirements for audiometers and particular requirements for pure-tone audiometers designed for use in determining hearing threshold levels, in comparison with standard reference threshold levels by means of psychoacoustic test methods.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to particular International Standards referenced herein:

Reference to International Standard		*Australian/New Zealand Standard*	
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	General requirements for safety—Parent Standard
60601-1-2	Part 1-2: General requirements for safety—Collateral Standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: General requirements for safety—Collateral Standard: Electromagnetic compatibility—Requirements and tests
ISO		AS/NZS	
389	Acoustics—Reference zero for the calibration of audiometric equipment	1591	Acoustics—Instrumentation for audiometry
389-3	Part 3: Reference equivalent threshold force levels for pure tones and bone vibrators	1591.1	Part 1: Reference zero for the calibration of pure-tone bone conduction audiometers

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INTRODUCTION

Developments in the field of hearing measurements for diagnostic, hearing conservation and rehabilitation purposes have resulted in the availability of a wide range of audiometers. In addition it is possible to consider the audiometer in terms of a set of functional units which can be specified independently. By specifying these functional units it is then possible to specify the performance of other audiometric equipment which uses these units. IEC 60645 consists of a number of parts. IEC 60645-1 is the first in the series and covers the requirements for pure tone audiometers.

Due to the development of the later parts of IEC 60645, part 1 now confines its scope solely to the requirements of pure tone audiometers. One consequence of this is that no reference is now made to the use of broad-band noise for masking. Requirements for broad-band masking noise now only relate to its use with speech signals as described in IEC 60645-2.

This second edition now specifies performance requirements separate from the test requirements to show conformity. Conformance to the specifications in this International Standard is demonstrated only when the result of a measurement, extended by the actual expanded uncertainty of measurement of the testing laboratory, lies fully within the tolerances specified in this International Standard extended by the values for U_{max} given in table 7. By this, the tolerances that are to be met by the manufacturer of an audiometer are essentially the same as in the first edition of IEC 60645-1, while the tolerances as applicable to the use of the audiometer are increased by U_{max} compared with those of the previous edition.

AUSTRALIAN STANDARD

Electroacoustics—Audiological equipment

Part 1:
Pure-tone audiometers (IEC 60645-1:2001, MOD)

1 Scope and object

This part of IEC 60645 specifies general requirements for audiometers and particular requirements for pure-tone audiometers designed for use in determining hearing threshold levels, in comparison with standard reference threshold levels by means of psychoacoustic test methods.

The object of this International Standard is to ensure:

a) that tests of hearing, particularly threshold, in the frequency range 125 Hz to 8 000 Hz on a given human ear performed with different audiometers which comply with this International Standard using methods described in ISO 8253-1 and ISO 6189 shall give substantially the same results;

b) that the results obtained represent a valid comparison between the hearing of the ear tested and the reference threshold of hearing;

c) that audiometers are classified according to the range of test signals they generate, according to the mode of operation or according to the complexity of the range of auditory functions they test.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 60645. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of IEC 60645 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

IEC 60268-3, *Sound system equipment – Part 3: Amplifiers*

IEC 60318-1, *Electroacoustics – Simulators of human head and ear – Part 1: Ear simulator for the calibration of supra-aural earphones*

IEC 60318-2, *Electroacoustics – Simulators of human head and ear – Part 2: An interim acoustic coupler for the calibration of audiometric earphones in the extended high frequency range*

IEC 60318-3, *Electroacoustics – Simulators of human head and ear – Part 3: Acoustic coupler for the calibration of supra-aural earphones used in audiometry*

IEC 60373, *Mechanical coupler for measurements on bone vibrators*

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

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