BS EN 61669:2016

BSI Standards Publication

Electroacoustics — Measurement of real-ear acoustical performance characteristics of hearing aids

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National foreword

This British Standard is the UK implementation of EN 61669:2016. It is identical to IEC 61669:2015. It supersedes BS ISO 12124:2001 and BS EN 61669:2001 which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EPL/29, Electroacoustics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2016

ISBN 978 0 580 82916 1
ICS 17.140.50

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 29 February 2016.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61669

February 2016

ICS 17.140.50

Supersedes EN 61669:2001

English Version

Electroacoustics - Measurement of real-ear acoustical performance characteristics of hearing aids (IEC 61669:2015)

Électroacoustique - Mesure des caractéristiques de performances acoustiques des appareils de correction auditive sur une oreille réelle (IEC 61669:2015)

Elektroakustik - Messung der Kenndaten von Hörgeräten am menschlichen Ohr (IEC 61669:2015)

This European Standard was approved by CENELEC on 2015-12-09. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 61669:2016 E

European foreword

The text of document 29/886/FDIS, future edition 2 of IEC 61699, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61699:2016.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-09-09
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-09

This document supersedes EN 61699:2001.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 61699:2015 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:

IEC 60118-0	NOTE	Harmonized as EN 60118-0.
IEC 60118-7	NOTE	Harmonized as EN 60118-7.
IEC 60118-8	NOTE	Harmonized as EN 60118-8.
IEC 60118-15	NOTE	Harmonized as EN 60118-15.
IEC 60318-4	NOTE	Harmonized as EN 60318-4.

Annex ZA
(normative)
Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60318-5	-	Electroacoustics - Simulators of human head and ear -- Part 5: 2 cm³ coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts	EN 60318-5	-
IEC 60601-1	-	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance	EN 60601-1	-
IEC 60601-1-2	-	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	-
IEC 60942	-	Electroacoustics - Sound calibrators	EN 60942	-
IEC 61260-1	-	Electroacoustics - Octave-band and fractional-octave-band filters -- Part 1: Specifications	EN 61260-1	-
ISO 266	-	Acoustics - Preferred frequencies	EN ISO 266	-
ISO 8253-2	-	Acoustics - Audiometric test methods - Part 2: Sound field audiometry with pure-tone and narrow-band test signals	EN ISO 8253-2	-
ISO/TR 25417	-	Acoustics_- Definitions of basic quantities and terms	-	-

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ELECTROACOUSTICS – MEASUREMENT OF REAL-EAR ACOUSTICAL PERFORMANCE CHARACTERISTICS OF HEARING AIDS

FOREWORD

International Standard IEC 61669 has been prepared by IEC technical committee 29: Electroacoustics.

This second edition cancels and replaces the first edition of IEC 61669:2001 and the first edition of ISO 12124:2001. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to IEC 61669:2001 and ISO 12124:2001:

a) the addition of the International Speech Test Signal as a preferred speech-like stimulus;
b) definitions and test methods for the real-ear to dial difference;
c) definitions and test methods for the real-ear to coupler difference and
d) an annex dealing with issues in the measurement and application of the real-ear to coupler difference;

The text of this standard is based on the following documents:

FDIS	Report on voting
29/886/FDIS	29/893/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The performance characteristics of hearing aids in actual use can differ significantly from those determined in accordance with standards such as IEC 60118-0, and IEC 60118-7, due to differing acoustic influence and coupling presented by individual ears. Measuring methods that take into account the acoustic coupling and the acoustic influence of the individual wearer on the performance of hearing aids are therefore important in the fitting of these devices. Such measuring methods have come to be known as “real-ear measurements” and are sometimes performed clinically in less than ideal acoustic environments. The accuracy and repeatability of measurements made under such conditions are complex functions of the sound field, the test environment, the nature of the test signal, the hearing aid under evaluation, the method of test signal control, the location of the sound field source, the nature of the data acquisition, analysis and presentation as well as the degree of subject movement permitted.

This standard provides definitions for terms used in the measurement of real-ear performance characteristics of hearing aids, provides procedural and reporting guidelines, and identifies essential characteristics to be reported by the manufacturer of equipment used for this purpose. Acceptable tolerances for the control and measurement of sound pressure levels are indicated. Where possible, sources of error have been identified and suggestions provided for their management.

ELECTROACOUSTICS – MEASUREMENT OF REAL-EAR ACOUSTICAL PERFORMANCE CHARACTERISTICS OF HEARING AIDS

1 Scope

This International Standard gives recommendations and requirements for the measurement and estimation of the real-ear acoustical performance characteristics of air-conduction hearing aids and for the measurement of certain acoustic properties of the ear related to the application of hearing aids.

Measurements of real-ear acoustical characteristics of hearing aids which apply non-linear or analytical processing techniques are valid only for the test signals used and conditions employed.

The purpose of this standard is to ensure that measurements of real-ear acoustical performance characteristics of a given hearing aid on a given human ear can be replicated in other locations with other test equipment.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60318-5, *Electroacoustics – Simulators of human head and ear – Part 5: 2 cm^3 coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts*

IEC 60942, *Electroacoustics – Sound calibrators*

IEC 61260-1, *Electroacoustics – Octave-band and fractional-octave-band filters – Part 1: Specifications*

ISO 266, *Acoustics – Preferred frequencies*

ISO 8253-2, *Acoustics – Audiometric test methods – Part 2: Sound field audiometry with pure-tone and narrow-band test signals*

ISO/TR 25417, *Acoustics – Definitions of basic quantities and terms*

3 Terms and definitions

For the purpose of this document, the terms and definitions of ISO/TR 25417 and the following apply:

3.1
test signal
acoustic signal at the field reference point

3.2
coupled sound source
earphone or hearing aid receiver and any tubing used to couple its acoustic output, without leakage, to the ear canal or the cavity of a coupler

3.3
free sound field
sound field where the boundaries of the room exert a negligible effect on the sound waves

Note 1 to entry: In practice, a free sound field is a field in which the influence of reflections at the boundaries or other disturbing objects is negligible over the frequency range of interest.

[SOURCE: ISO 8253-2:2009, 3.12, modified (addition of note to entry)]

3.4
quasi-free sound field
sound field where the boundaries of the room exert only a moderate effect on the sound waves

[SOURCE: ISO 8253-2:2009, 3.13]

3.5
subject
person in whose ear the hearing aid performance is characterized

3.6
subject reference point
point bisecting the line joining the centres of the openings of the ear canals of the subject (at the junction between concha and ear canal)

Note 1 to entry: In cases where severe head shape abnormality or asymmetry make it difficult to determine the reference point of the subject, the subject reference point used should be stated.

3.7
subject test position
position with subject seated in a reproducible upright position with the head erect and the subject reference point located on the test axis at the working distance

3.8
test axis
line through the centre of the surface from which sound exits the sound field source and in the direction of maximum acoustic radiation

SEE: Figure 1.

3.9
test point
reproducible position on the test axis at which the subject reference point is located for test purposes

SEE: Figure 1.

3.10
working distance
distance from the subject reference point to the plane of the mounting ring or protective grille of the sound field source measured along the test axis

SEE: Figure 1.

3.11
SPL
sound pressure level
ten times the logarithm to the base 10 of the ratio of the square of the sound pressure, p, to the square of a reference value, p_0

$$L_p = 10\lg(p^2/p_0^2) \text{ dB}$$

where the reference value, p_0, is 20 μPa

Note 1 to entry: Sound pressure level is expressed in decibels.

Note 2 to entry: Because of practical limitations of the measuring instruments, p^2 is always understood to denote the square of a frequency-weighted, frequency-band-limited or time-weighted sound pressure.

Note 3 to entry: This note applies to the French version only.

[SOURCE: ISO/TR 25417:2007, 1.2]

3.12
BSPL
band sound pressure level
SPL for a specified frequency band

Note 1 to entry: This note applies to the French language only.

3.13
test signal level
SPL of the test signal at the field reference point

Note 1 to entry: For broad-band signals the bandwidth of the SPL measurement and the BSPL as a function of frequency should be specified and stated.

3.14
equalization
process of controlling the test signal level as a function of frequency such that it does not vary from the desired level

3.14.1
concurrent equalization
real time equalization
equalization performed at the time of measurement based on the monitoring of the test signal level

3.14.2
stored equalization
equalization performed at the time of measurement based on data recorded during a prior measurement of the sound field

3.15
reference microphone
controlling microphone
microphone used to measure the test signal level in the measurement process and/or to control it in the equalization process

SEE: Figure 2.

3.16
sound inlet
aperture through which sound enters a microphone and at which the microphone is calibrated

3.17
field reference point
point at which the sound inlet of the reference microphone is located during equalization and/or measurement

SEE: Figure 2.

3.18
probe microphone
microphone adapted to explore a sound field without significantly disturbing it

Note 1 to entry: If the probe microphone utilizes a probe tube; this tube is considered part of the probe microphone and its open end is the probe microphone sound inlet.

3.19
test ear
ear of the subject in which the probe microphone sound inlet is placed

3.20
measurement point
point in the ear canal of the test ear at which the probe microphone sound inlet is placed

3.21
axis of rotation
straight line about which the subject can be rotated, passing through the subject reference point and lying in the vertical plane of symmetry

SEE: Figure 1.

3.22
azimuth angle of sound incidence
angle between the plane of symmetry of the subject and the plane defined by the axis of rotation and the test axis

SEE: Figure 1.

Note 1 to entry: When the subject faces the sound field source, the azimuth angle of sound incidence is defined as 0°. When the test ear of the subject faces the sound field source, the azimuth angle is defined as 90°. When the non-test ear faces the sound field source, the angle is defined as –90°.

3.23
subject reference plane
horizontal plane that contains the subject reference point

SEE: Figure 1.

3.24
elevation angle of sound incidence
angle between the subject reference plane and the test axis

SEE: Figure 1.

Note 1 to entry: When the sound field source is directly above the subject, the elevation angle is defined as +90°. When the test axis lies in the subject reference plane, the elevation angle is defined as 0°.

3.25
test signal type
identification of the test signal in terms of its frequency spectrum and/or temporal properties

3.26
maximum length sequence
MLS
periodic pseudo-random binary sequence of length one less than an integer power of two, whose circular autocorrelation function is an impulse

Note 1 to entry: This note applies to the French language only.

3.27
substitution method
method of measurement using stored equalization with the reference microphone located at the subject reference point and the subject absent during the recording of the SPL at the test point

3.28
modified pressure method
method of measurement using stored or concurrent equalization with the field reference point near the surface of the head of the subject close to the test ear, but outside the acoustic influence of the pinna and the hearing aid

Note 1 to entry: The exact location of the field reference point should be specified by its perpendicular distance from the surface of the head and its distance (in millimetres) forward of and above or below the centre of the ear canal entrance.

3.29
differential comparison
measurement in which the test signal level is subtracted from the SPL at the measurement point

Note 1 to entry: When using broad-band signals, BSPL should be used.

3.30
real-ear unaided response
REUR
SPL as a function of frequency at the measurement point in the unoccluded ear canal for a specified test signal level

Note 1 to entry: When using broad-band signals, BSPL should be used.

Note 2 to entry: This note applies to the French language only.

3.31
real-ear unaided gain
REUG
difference, as a function of frequency, between the SPL at the measurement point in the unoccluded ear canal and the test signal level

Note 1 to entry: When using broad-band signals, BSPL should be used.

Note 2 to entry: This note applies to the French language only.

3.32
real-ear occluded response
REOR
SPL as a function of frequency at the measurement point for a specified test signal level, with the hearing aid in place and switched off

Note 1 to entry: This note applies to the French language only.

3.33
real-ear occluded gain
REOG
difference as a function of frequency, between the SPL at the measurement point and the test signal level, with the hearing aid in place and switched off

Note 1 to entry: When using broad-band signals, BSPL should be used.

Note 2 to entry: This note applies to the French language only.

3.34
real-ear aided response
REAR
SPL as a function of frequency at the measurement point for a specified test signal level, with the hearing aid in place and switched on

Note 1 to entry: The term Real-Ear Saturation Response (RESR) has sometimes been used for the REAR with a stimulus SPL of 85 dB or 90 dB. The use of this term is deprecated in favour of REAR85 or REAR90.

Note 2 to entry: This note applies to the French language only.

3.35
real-ear aided gain
REAG
difference as a function of frequency, between the SPL at the measurement point and the test signal level, with the hearing aid in place and switched on

Note 1 to entry: When using broad-band signals, BSPL should be used.

Note 2 to entry: This note applies to the French language only.

3.36
real-ear insertion gain
REIG
difference as a function of frequency, between aided response and unaided response ($REIG = REAR - REUR$), or between aided gain and unaided gain ($REIG = REAG - REUG$)

Note 1 to entry: It is assumed that REAR and REUR have been derived using the same test signal.

Note 2 to entry: REIG is expressed in decibels.

Note 3 to entry: This note applies to the French language only.

3.37
real-ear to coupler difference
RECD
difference as a function of frequency, between the SPL produced near the tympanic membrane in an occluded ear canal by a coupled sound source having a high acoustic impedance and that produced in the 2 cm^3 coupler specified in IEC 60318-5 by the same coupled sound source connected directly to its cavity

Note 1 to entry: This note applies to the French language only.

3.38
real-ear to dial difference
REDD
difference as a function of frequency, between the SPL produced near the tympanic membrane by an audiometric sound source and the hearing level indicated by the audiometer driving the sound source

Note 1 to entry: This note applies to the French language only.

3.39
curve
real-ear acoustical characteristic expressed and graphically displayed as a function of frequency

EXAMPLE Real-ear aided response curve.

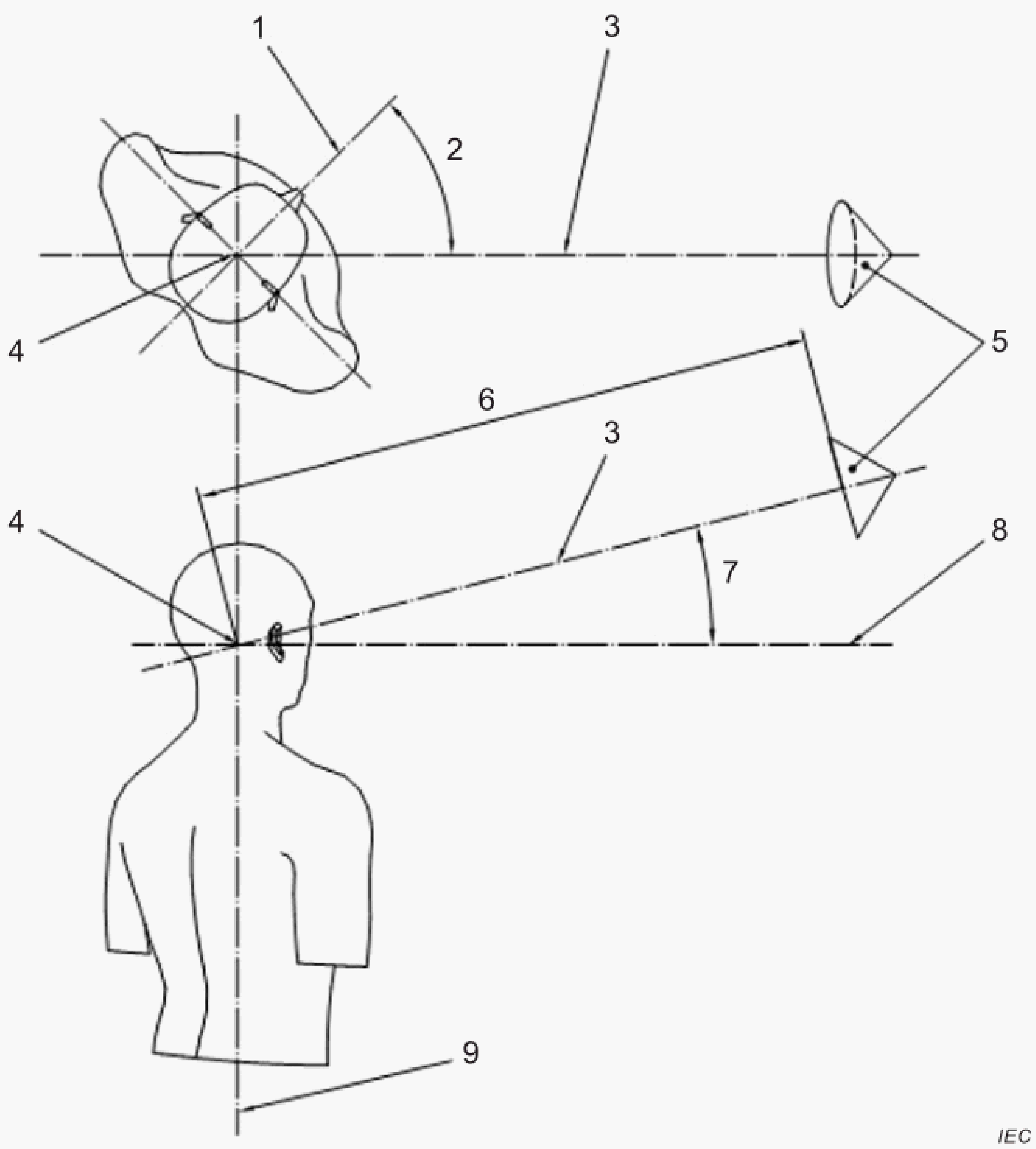
3.40
crest factor
ratio of the peak sound pressure to the root-mean-square sound pressure of the test signal

Note 1 to entry: When expressed in decibels, crest factor is the difference between the peak and r.m.s levels of the test signal.

3.41
long term average speech spectrum
LTASS
SPL in contiguous one-third-octave bands measured over the duration of a speech sample

4 Test setup diagrams

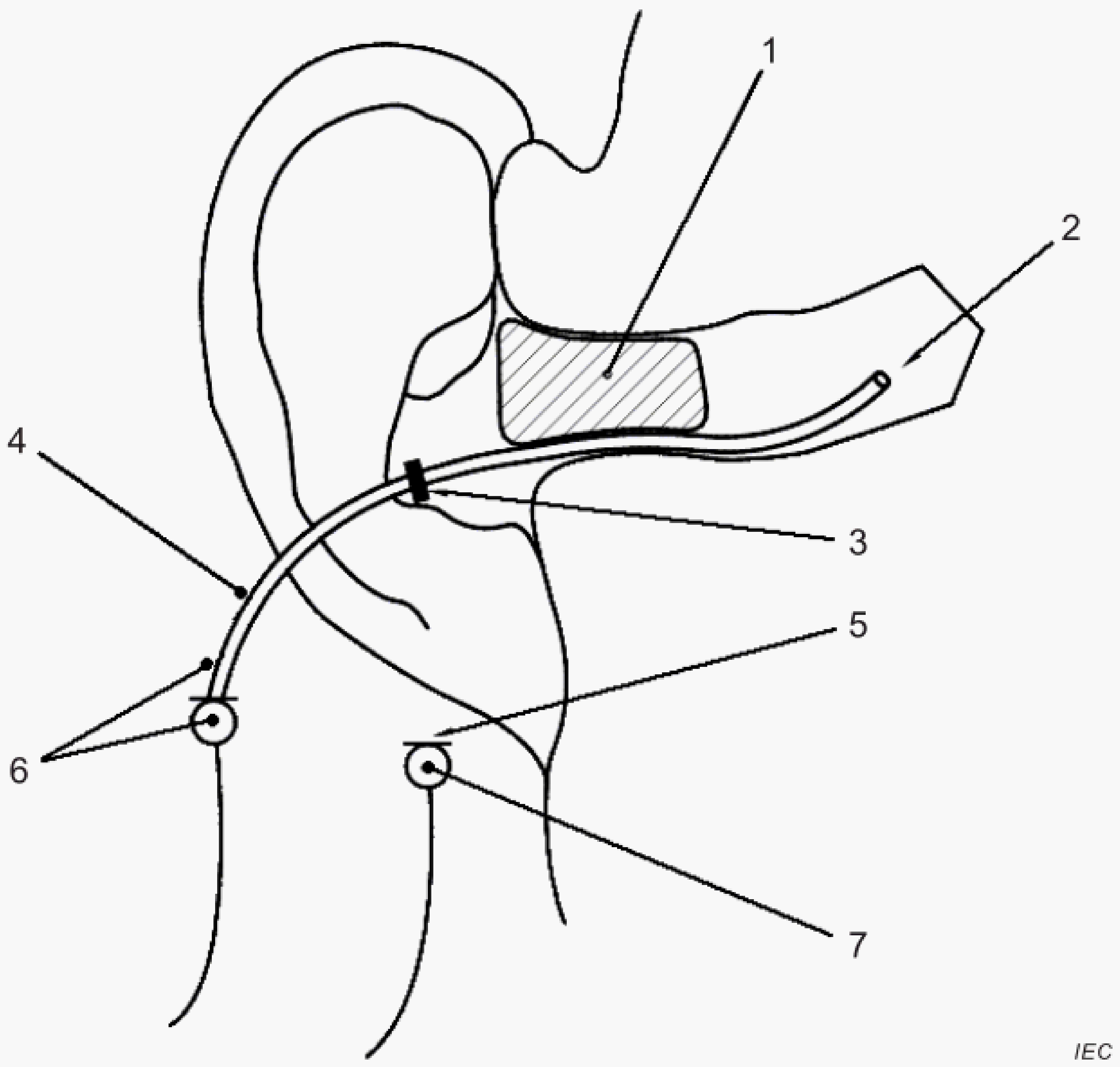
The following two figures illustrate the relationship between the subject and the parts of the measurement system that deliver and receive sound.



Key

1 Plane of symmetry
2 Azimuth angle of sound incidence
3 Test axis
4 Subject reference point and Test point
5 Sound source
6 Working distance
7 Elevation angle of sound incidence
8 Subject reference plane
9 Axis of rotation

Figure 1 – Test set-up



Key

1 Hearing aid or earmould

2 Measurement point and probe microphone sound inlet

3 Marking or marking device

4 Probe tube (part of probe microphone)

5 Field reference point

6 Probe microphone (includes a probe tube if used)

7 Reference microphone

Figure 2 – Real-ear measurement arrangement

5 Limitations

Measurements of real-ear acoustical performance characteristics of hearing aids are influenced by the following factors:

- type of hearing aid,
- test signal,
- method of equalization,
- test environment,
- signal analysis characteristics
- result analysis and presentation,
- degree of subject movement permitted,
- hearing aid – subject interface,
- physical characteristics of the subject.

6 Test equipment

6.1 Safety requirements

Equipment shall conform to the requirements of IEC 60601-1 and IEC 60601-1-2.

6.2 Ambient conditions

Performance requirements shall be met for the following ambient conditions:

Temperature:	18 °C to 28 °C
Relative humidity:	20 % to 80 %
Atmospheric pressure:	81,3 kPa to 106,3 kPa

If other conditions apply, these conditions shall be stated. If the calibration of the measurement system depends on ambient conditions, corrections for such dependence shall be made.

6.3 Test signal

The equipment manufacturer shall report the test signal type(s) provided by the equipment and shall supply the information listed below for each type. For hearing aids employing advanced signal processing techniques the International Speech Test Signal (ISTS) specified in IEC 60118-15 should be used.

For a pure-tone test signal, report the frequency spacing (if stepped) and total harmonic distortion.

For a tone burst, report the frequency spacing (if stepped), the ON and OFF times for the burst, the number of repetitions at each frequency and the SPL during the ON time of the tone burst.

For a warble tone test signal, report the frequency spacing (if stepped), modulating frequency, frequency deviation, and type of modulating waveform.

For a narrow-band noise test signal, report the frequency spacing (if stepped), effective bandwidth, slope of band skirts, and the spacing of frequency components within the band (if pseudo-random).

For a random noise test signal, report the crest factor and frequency spectrum employed.

For pseudo-random noise, chirp, and click test signals, report the spacing and number of frequency components, lowest frequency present, frequency spectrum employed, repetition rate, and crest factor.

For an MLS test signal, report order, sampling rate, crest factor, and frequency spectrum employed.

For a speech-like test signal, report the test signal level and the bandwidth over which it is determined, the LTASS and, if digitized, the sampling rate and number of bits. If the test signal is standardized or commercially available, report the source and identifying information. The International Speech Test Signal (ISTS) specified in IEC 60118-15 is the preferred speech-like test signal.

If the speech has been modified by other than linear filtering, a description of the processing or a reference where it can be found should be provided.

Measurements of real-ear acoustical performance characteristics of hearing aids which use non-linear or analytical processing techniques are valid only for the test signals and conditions employed. These measurements should be performed in accordance with the hearing aid manufacturer's recommendations, as they can require specific test signals or test conditions outside the scope of this standard.

6.4 Sound field source

When using the substitution method, the sound field source shall consist only of coaxial elements. In order to avoid reflections, the frontal surface of the sound field source enclosure shall be covered with a suitable absorbing material. When using the modified pressure method these restrictions do not apply.

6.5 Coupled sound source

The magnitude of the acoustic impedance of the coupled sound source used in the measurement of the RECD shall be at least 3.16 times that of the occluded test ear and of the 2 cm^3 coupler.

6.6 Test signal range

Narrow-band test signal levels shall cover the range from 50 dB to 90 dB at a working distance of 0,5 m in an anechoic environment, with a maximum step size of 5 dB.

6.7 Test signal level indication

For the range of levels indicated by the equipment manufacturer, when measured at the inlet to the reference microphone, the indicated test signal level as a function of frequency shall be accurate within 4 dB.

6.8 Equalization

In an anechoic environment, equalization shall allow the test signal to be controlled, as a function of frequency, to within 4 dB of the intended test signal level at the field reference point at a working distance of 0,5 m.

6.9 Frequency

The frequency, or components, of the test signal shall cover the frequency range from 200 Hz to 8 000 Hz (i.e. covering the one-third octave bands from 250 Hz to 6 300 Hz).

The indicated frequency of a narrow-band test signal or the indicated centre frequency of the analysis bands for a broad-band test signal shall be accurate within 3 %.

6.10 Harmonic distortion

For a pure-tone test signal in an anechoic environment, the total harmonic distortion of the test signal at the field reference point at a working distance of 0,5 m shall not exceed 3 %.

6.11 Probe microphone measurement

For the measurement range indicated by the equipment manufacturer, the probe microphone measurement shall be accurate within 4 dB over the frequency range 200 Hz to 8 000 Hz (i.e. covering the one-third-octave bands from 250 Hz to 6 300 Hz).

6.12 Noise floor of probe microphone measurement

When the probe microphone sound inlet is acoustically sealed, the indicated SPL, as a function of frequency, shall be at least 10 dB below the lowest level to be measured over the frequency range 200 Hz to 8 000 Hz, for pure tones, or in the one-third-octave bands from 250 Hz to 6 300 Hz for broad-band signals.

Care shall be taken to avoid errors caused by extraneous noise when verifying this indication.

6.13 Attenuation of probe microphone to external signals

When the probe microphone sound inlet is acoustically sealed and placed in a sound field, the SPL, as a function of frequency, measured by the probe microphone, shall be at least 10 dB lower than the lowest level to be measured with the sound inlet open, over the frequency range 200 Hz to 8 000 Hz, for pure tones, or in the one-third octave bands from 250 Hz to 6 300 Hz for broad-band signals.

The sound field used for this measurement shall be uniform over the surface of the entire probe microphone and of sufficient level to cause the measured SPL to exceed the noise floor of the probe microphone by at least 10 dB.

6.14 Analysis characteristics

The equipment manufacturer shall report the analysis type(s) employed by the equipment and shall supply the information listed below for each type.

For analysis of a tone-burst test signal, report the integration time of the SPL measurement if different from the ON time of the tone-burst.

For broad-band analysis, report the measurement bandwidth and integration time.

For spectrum analysis employing a swept filter, report the filter bandwidth and skirt slope.

For spectrum analysis employing digital means, report sampling rate, digital resolution, averaging time or number of averages, analysis bandwidth, block length, windowing type, window overlap, method (synchronous, FFT auto-spectrum, FFT cross-spectrum, digital filter), and total frequency range of analysis. For analysis using a digital filter bank, report centre frequencies, bandwidth and integration times. Octave or fractional-octave band filters should conform to IEC 61260 Class 2.

Preferred frequencies are the one-third-octave frequencies specified in ISO 266.

6.15 Output indication

The output indicator used shall give r.m.s. value indication within 2 dB of the true r.m.s. value for the type of signal to be measured.

If, under certain conditions, it is necessary to use a selective measuring system, e.g. filtering, to ensure that the response of the hearing aid to the test signal can be differentiated from inherent noise in the hearing aid, the use of the selective system should be stated in the report.

NOTE The type of output indicator employed can influence the test results significantly if a non-sinusoidal voltage is being measured. Such non-sinusoidal voltages can be present when making measurements with high input levels to the hearing aid.

6.16 Graphical printout

It is recommended that frequency response curves be plotted on a grid having a linear decibel ordinate scale and a logarithmic frequency abscissa scale with the length of one decade on the abscissa scale equal to the length of (50 ± 2) dB on the ordinate scale.

7 Test conditions

7.1 Ambient conditions in the test space

The operator shall ensure that the equipment has reached a stable operating condition and that ambient conditions in the test space at the time of test are within the ranges specified in 6.2. If other conditions apply, these conditions shall be stated. If the calibration of the measurement system depends on ambient conditions, corrections for such dependence shall be made in accordance with instructions provided by the equipment manufacturer or as determined by the operator.

7.2 Background noise

At the field reference point, the signal shall exceed the background noise at every analysis frequency (or in every analysis band) by at least 10 dB. Background noise at frequencies outside the analysis range shall not affect measured results by more than 1 dB.

NOTE Background noise at frequencies outside the analysis range can activate automatic gain regulating circuitry or cause saturation in the hearing aid under test.

7.3 Acoustical properties

The physical size and absorption characteristics of the test space influence the accuracy of real-ear measurements. The extent of this influence depends upon the test signal used, the working distance, the method of sound field equalization, subject movement, and the type of hearing aid being tested. In order to minimize errors due to reflected sound, the field reference point should be chosen such that the distance from both the field reference point and the sound field source to the nearest reflective surface is at least twice the working distance.

7.4 Sound field characteristics

The environments in which measurements are made can vary considerably. A free sound field is preferred but a quasi-free sound field may be used. The type of sound field used shall be stated. The test space shall allow the test signal level to be controlled to within 3 dB of the desired test signal level.

7.5 Calibration

Pretest calibration of the test equipment shall be carried out directly, using a calibrator complying with IEC 60942, or indirectly following the manufacturer's instructions. Any setting-up procedures should also be performed in accordance with the manufacturer's instructions.

At least annually, the calibration of the reference microphone shall be verified by coupling it to a calibrator complying with IEC 60942 using a suitable adapter supplied or specified by the equipment manufacturer.

7.6 Equalization

7.6.1 General

The test system shall be equalized prior to a test, and as otherwise indicated in 7.6.2 to 7.6.4, using one of the methods of this subclause. The equalization method used shall be stated.

7.6.2 Substitution method

Following the equipment manufacturer's instructions, record the test signal at the test point with the subject absent. The recording shall be updated whenever there is a change in the acoustic environment. This method requires a free sound field such as can be achieved in an anechoic chamber.

7.6.3 Modified pressure method – Stored equalization

Place the subject in the test position. Following the equipment manufacturer's instructions, record the test signal at the field reference point. All objects that will be present during subsequent tests should be in position (including the operator). The recording shall be updated whenever there is a change in the test point, the field reference point, or the acoustic environment.

7.6.4 Modified pressure method – Concurrent equalization

Equalization is not a separate step but occurs automatically during measurement by monitoring the signal from the reference microphone at the field reference point.

Sound outflow from a large vent or open fitting can interfere with the concurrent equalization process. In this case, it can be necessary to employ stored equalization with the hearing aid switched off or muted during the recording of the test signal. The manufacturer’s instructions in this regard should be followed.

7.7 Test signal level

The test signal level shall be chosen with concern for subject safety and comfort, the ambient background noise and the characteristics of the hearing aid under test. The level used shall be stated.

Special consideration shall be given to hearing aids with automatic gain control circuitry or which apply other non-linear signal processing techniques. When it is desired to test hearing aid performance in the linear operating region, the lowest possible test signal level should be used. Linearity should be verified by observing that over the frequency range 200 Hz to 8 000 Hz, or as otherwise desired, a change in test signal level causes the same change at the measurement point. The frequency range used shall be stated.

NOTE The SPL presented to the hearing aid microphone can significantly exceed the test signal level because of the location of the hearing aid microphone and subject position.

7.8 Location of the subject

The subject shall be located in the subject test position during all measurements except the initial sound field recording of the substitution method. A minimum working distance of 0,5 m, an elevation angle of sound incidence of 0° and an azimuth angle of sound incidence of 0° or 45° are recommended. Working distance, elevation and azimuth angles of sound incidence shall be stated.

7.9 Location of the tester

The tester shall remain at least 1 m from the test ear during testing and during equalization if using the method of 7.6.3.

7.10 Location of the field reference point

This point may be recommended by the manufacturer or dictated by the physical construction of the equipment. The results of the measurements (REUR, REUG, REAR, REAG, REOR and REOG) depend upon the choice of field reference point. For these measurements, the exact location of the field reference point is to be specified by its perpendicular distance (in mm) from the surface of the head, and its distance (in mm) forward of and above or below the centre of the ear canal entrance. For devices operating linearly, REIG is independent of the field reference point. When concurrent equalization is used, care shall be taken to ensure that the presence of the hearing aid during the aided measurement does not alter the signal being produced by the sound field source.

7.11 Location of the measurement point

An otoscopic examination of the ear canal should be performed by a qualified person, prior to insertion of the probe microphone sound inlet into the ear canal, to identify excess cerumen and any abnormalities contra-indicating the use of the ear for test purposes.

The measurement point shall be chosen such that a ±2 mm change in its position shall produce a change of less than 2 dB in the measurement of interest over the frequency range 200 Hz to 6 000 Hz. For unoccluded measurements, this will generally require that the measurement point be within 6 mm of the tympanic membrane. Occluded measurements will, in general, additionally require that the measurement point be at least 5 mm beyond the sound outlet of the hearing aid or earmould (see Annex A). These conditions cannot always be met for deeply inserted earmoulds or hearing aids.

When locating the probe microphone sound inlet at the measurement point, care should be taken to ensure the subject does not experience any discomfort.

NOTE Further information regarding the positioning of the probe microphone sound inlet can be found in Annex A.

7.12 Instructions to the subject

Information on the test procedure shall be given unambiguously to the subject and should be fully understood. The subject shall be instructed to remain silent and avoid unnecessary movement during the measurements. The subject shall also be informed that he/she may interrupt the test at any time in the case of discomfort.

7.13 Location and coupling of the hearing aid

The hearing aid shall be placed on the subject and acoustically coupled to the ear canal in the manner of normal use. Care should be taken to avoid movement of the probe microphone sound inlet, blocking or compressing the probe tube or creating an acoustic leak around the hearing aid or earmould. Venting, if present, should be as normally used. The acoustic coupling to the ear canal shall be stated. It is recommended that the hearing aid be fitted with a fresh battery or operated from power provided by its programming device.

NOTE Leakage around the probe tube can be avoided by providing a vent for probe tube insertion which can be sealed after use. The latter also prevents probe tube collapse.

The probe tube may be inserted through a vent used for acoustic modification if the vent diameter is at least 3 times the external diameter of the probe tube.

7.14 Operating conditions for the hearing aid

For REOR and REOG measurements, the hearing aid shall be switched off. For other measurements, the settings of all controls or programming shall be stated.

8 Measurements

8.1 General

The test conditions of Clause 7 apply to the measurements of this clause.

8.2 Real-ear unaided response (REUR) curve

With the test ear unoccluded, follow the equipment manufacturer's instructions to record a curve of SPL at the measurement point. This is the REUR curve.

NOTE When using broad-band signals, a curve of BSPL is recorded.

The method of equalization shall be stated. The location of the field reference point shall be reported as described in 7.10.

If this measurement will be used in a REIG calculation, the field reference point, the test signal and the measurement point shall be the same as that used in the REAR measurement.

8.3 Real-ear unaided gain (REUG) curve

With the test ear unoccluded, follow the equipment manufacturer's instructions to record a curve of SPL at the measurement point relative to the test signal level. This is the REUG curve.

NOTE When using broad-band signals, a curve of BSPL relative to the test signal BSPL is recorded.

The method of equalization shall be stated. The location of the field reference point shall be reported as described in 7.10.

If this measurement will be used in a REIG calculation, the field reference point and the measurement point shall be the same as that used in the REAG measurement.

8.4 Real-ear occluded response (REOR) curve

With the hearing aid or earmould in the test ear and the hearing aid switched off, follow the equipment manufacturer's instructions to record a curve of SPL at the measurement point. This is the REOR curve.

NOTE When using broad-band signals, a curve of BSPL is recorded.

The method of equalization shall be stated. The location of the field reference point shall be reported as described in 7.10.

8.5 Real-ear occluded gain (REOG) curve

With the hearing aid in the test ear and switched off, follow the equipment manufacturer's instructions to record a curve of SPL at the measurement point relative to the test signal. This is the REOG curve.

NOTE When using broad-band signals, a curve of BSPL relative to the test signal BSPL is recorded.

The method of equalization shall be stated. The location of the field reference point shall be reported as described in 7.10.

8.6 Real-ear aided response (REAR) curve

With the hearing aid or earmould in the test ear and the hearing aid switched on and set to desired settings, follow the equipment manufacturer's instructions to record a curve of SPL at the measurement point. This is the REAR curve.

NOTE When using broad-band signals, a curve of BSPL is recorded.

The method of equalization shall be stated. The location of the field reference point shall be reported as described in 7.10.

Sound outflow from a large vent or open fitting can interfere with the concurrent equalization process. In this case, it can be necessary to employ stored equalization with the hearing aid switched off or muted during the recording of the test signal. The manufacturer's instructions in this regard should be followed.

8.7 Real-ear aided gain (REAG) curve

With the hearing aid or earmould in the test ear and the hearing aid switched on and set to desired settings, follow the equipment manufacturer's instructions to record a curve of SPL at the measurement point relative to the test signal level. This is the REAG curve.

NOTE When using broad-band signals, a curve of BSPL is recorded.

The method of equalization shall be stated. The location of the field reference point shall be reported as described in 7.10.

Sound outflow from a large vent or open fitting can interfere with the concurrent equalization process. In this case, it can be necessary to employ stored equalization with the hearing aid switched off or muted during the recording of the test signal. The manufacturer's instructions in this regard should be followed.

8.8 Real-ear insertion gain (REIG) curve

To obtain the REIG curve:

a) subtract the REUR curve from the REAR curve, or
b) subtract the REUG curve from the REAG curve.

8.9 Real-ear to coupler difference (RECD) curve

Use a coupled sound source meeting the requirements of 6.5 and:

a) With the coupled sound source sealed directly to the cavity of a 2 cm^3 coupler in accordance with IEC 60318-5, follow the manufacturer's instructions to record a curve of the SPL in the coupler.
b) With the probe microphone sound inlet at the measurement point in the ear canal, seal the coupled sound source to the ear canal and follow the manufacturer's instructions to record a curve of the SPL in the occluded ear.
c) Subtract the recorded coupler SPL from the recorded ear canal SPL to obtain the RECD.

NOTE 1 When using broad-band signals, curves of BSPL are recorded.

NOTE 2 See Annex B for potential sources of error in measuring and applying the RECD.

8.10 Real-ear to dial difference (REDD) curve

To measure the REDD curve for an individual subject:

a) Place the probe microphone sound inlet at the measurement point.
b) If a sound-field audiometer is being used, position the subject at the same location used for audiometric tests. If earphones or insert earphones are being used, position them on or in the subject's ears, being careful not to change the location of the probe microphone sound inlet.
c) Select a test frequency on the audiometer.
d) Set the hearing level (HL) on the audiometer to 70 dB and present a continuous signal.
e) Deduct 70 dB from the probe microphone measurement and record this as the REDD at the selected frequency.
f) Repeat for other frequencies of interest.
g) Add the REDD to the behavioural measure, for example the hearing threshold, etc., obtained using this audiometer.

9 Measurement uncertainty for the performance requirements of Clause 6

Conformance to the performance requirements in Clause 6 is demonstrated when a measured deviation from the stated requirement equals or does not exceed the acceptance limits for that requirement, provided also that the uncertainty of the measurement used to assess conformance does not exceed the maximum permitted uncertainty (U_{max}) in Table 1.

Table 1 – Tolerance limits, acceptance limits and U_{max} for basic measurements

Measured quantity	Subclause(s)	Acceptance limit(s)	U_{max}
Test signal SPL or BSPL	6.7, 6.8	± 3 dB	1,0 dB
Probe microphone SPL or BSPL	6.11	± 3 dB	1,0 dB
Frequency	6.9	± 2 %	0,5 %
Total harmonic distortion	6.10	≤ 2 %	1,0 %

Annex A
(informative)

Positioning the probe microphone sound inlet at the measurement point

A.1 General

This annex suggests some methods that can be used to position the probe microphone sound inlet at the preferred measurement point in the test ear. Although it is appreciated that the subsequent insertion of a hearing aid or earmould can result in slight movement of the measurement point, it is assumed that, once positioned, the probe microphone sound inlet remains fixed for all measurements.

To achieve the measurement conditions specified in 7.11 it is generally required that the probe microphone sound inlet be within 6 mm of the tympanic membrane and at least 5 mm beyond the sound outlet of the hearing aid. These conditions cannot always be met for deeply inserted earmoulds or hearing aids, making it necessary for the probe microphone sound inlet to be within 5 mm of the hearing aid sound outlet.

Refer to the precautions of 7.11 regarding otoscopic examination and patient comfort.

A.2 Visual positioning

Using a marker or marking device, which can be supplied by the manufacturer, mark the probe microphone about 30 mm from its sound inlet. This length can be adjusted to accommodate longer or shorter ear canals as appropriate.

Insert the probe microphone sound inlet into the ear canal until the marking is adjacent to the intertragal notch. The canal can be straightened by deflection of the pinna to assist insertion.

Using an otoscope visually inspect the position of the probe microphone sound inlet and readjust to the desired measurement point if necessary.

If necessary, move the position of the marker.

A.3 Acoustically-assisted positioning

Insert the probe microphone sound inlet as described under Clause A.2.

Record the real-ear unaided gain or real-ear unaided response and observe the measurement in the region above 4 kHz.

Move the probe microphone sound inlet towards the tympanic membrane by 2 mm and repeat the above measurements observing any change in the region above 4 kHz.

If there is no significant difference between the first and second measurements the probe microphone sound inlet is now at the desired measurement point and the probe microphone should be marked accordingly.

If there is significant change the probe microphone sound inlet can be moved a further 2 mm closer to the tympanic membrane and the measurements repeated.

When the desired measurement point has been located, the position of the probe microphone can be marked accordingly.

A.4 Acoustic positioning – Method 1

Present a continuous 6 kHz narrow-band test signal with an SPL of 70 dB and continuously record the probe microphone measurement.

Carefully insert the probe microphone sound inlet into the ear canal entrance while observing the probe microphone measurement.

Slowly move the probe microphone sound inlet further into the canal while continually observing the probe microphone measurement. The measured level will reduce as the sound inlet reaches a point about 14 mm from the tympanic membrane and then increase again as the sound inlet is inserted further into the canal.

Observe the position of the probe microphone sound inlet which results in the minimum reading and insert it a further 8 mm from this point.

Care can be required to minimise the influence of the tester's hand on the measurement. This method can also be carried out using a swept test signal while observing the measured level in the 6 kHz region.

A.5 Acoustic positioning – Method 2

Equipment can facilitate an acoustic positioning method which utilises the monitoring of standing waves and outphasing during the probe microphone sound inlet insertion, where measurements made at frequencies above 8 kHz can be displayed. If available the following method can be used.

Select the appropriate measurement mode as specified by the manufacturer.

Slowly move the sound inlet of the probe microphone further into the ear canal while continually observing the displayed probe microphone measurement curve. When valleys appear on the measurement curve at frequencies above 8 kHz, the probe microphone sound inlet will be positioned approximately 5 mm to 10 mm from the eardrum.

This method can require care as the possible overlapping of peaks and valleys can cancel each other and the presence of valleys can be obscurred on the displayed measurement curve.

A.6 Geometrical positioning

Locate the surface of the hearing aid or earmould which corresponds to the position of the subject's ear canal floor leading to the intertragal notch.

Lay the probe microphone along this surface with its sound inlet positioned 5 mm beyond the tip of the hearing aid or earmould.

Mark the point on the probe microphone which corresponds to the position of the intertragal notch on the outer surface of the earmould or hearing aid. Reinsert the probe microphone sound inlet into the ear canal until the marker is adjacent to the intertragal notch.

Annex B
(informative)

Issues in RECD measurement and application

B.1 General

In clinical practice it is desirable, and frequently assumed, that the RECD is a property of the ear alone and is independent of the coupled sound source used in its measurement. This is the case only under certain limited conditions.

The RECD is used clinically for the following purposes.

a) Estimating the SPL produced near the tympanic membrane by a hearing aid from the SPL it produces in a 2 cm^3 coupler and, conversely, establishing targets for the SPL produced by a hearing aid in a 2 cm^3 coupler to achieve a desired SPL near the tympanic membrane.

b) Correcting an HL audiogram measured with insert earphones and a standard eartip for differences between the acoustic impedance of the individual ear and that of an average adult ear for which the insert earphones have been calibrated.

c) Correcting an HL audiogram measured with insert earphones and a custom earmould for differences between the earmould tubing and that of the standard eartip for which the insert earphones have been calibrated.

The purpose of this annex is to advise users of the RECD of the potential sources of error in measuring and applying it for these purposes. The figures used in this annex to illustrate the factors which influence the RECD have been generated by computer simulation.

B.2 Influence of the coupled sound source

When the SPL in the ear canal and in the 2 cm^3 coupler are measured using two different coupled sound sources, the ear canal to coupler level difference (ECLD) can be derived as:

$$ECLD = L_{\mathrm{pe}} - L_{\mathrm{pc}} = 20\lg\left|\frac{p_{\mathrm{se}}}{p_{\mathrm{sc}}}\right| \mathrm{dB} + 20\lg\left|\frac{Z_{\mathrm{e}}}{Z_{\mathrm{c}}}\right| \mathrm{dB} + 20\lg\left|\frac{Z_{\mathrm{sc}}+Z_{\mathrm{c}}}{Z_{\mathrm{se}}+Z_{\mathrm{e}}}\right| \mathrm{dB} \quad \text{(B.1)}$$

Where:

L_{pe} is the SPL produced in the ear canal by its coupled sound source;

L_{pc} is the SPL produced in the 2 cm^3 coupler by its coupled sound source;

p_{se} is the sound pressure of the sound source coupled to the ear canal;

p_{sc} is the sound pressure of the sound source coupled to the 2 cm^3 coupler cavity;

Z_{e} is the complex acoustic impedance of the occluded ear;

Z_{c} is the complex acoustic impedance of the 2 cm^3 coupler cavity;

Z_{sc} is the complex acoustic impedance of the sound source coupled to the 2 cm^3 coupler cavity;

Z_{se} is the complex acoustic impedance of the sound source coupled to the ear canal.

In this expression, only the $20\lg\left|\frac{Z_{\mathrm{e}}}{Z_{\mathrm{c}}}\right|$ term is independent of the coupled sound source used in its measurement. The additional terms introduce dependency on the ratio of the sound pressures of the two coupled sound sources and their complex acoustic impedances.

When the same coupled sound source is used in both the ear canal and 2 cm^3 coupler SPL measurement, p_{se} = p_{sc} and Z_{se} = Z_{sc} = Z_s and Equation (B.1) is reduced to:

$$ECLD = 20\lg\left|\frac{Z_e}{Z_c}\right| \text{dB} + 20\lg\left|\frac{Z_s+Z_c}{Z_s+Z_e}\right| \text{dB} \quad \text{(B.2)}$$

In this case, the ECLD no longer depends on the ratio of the sound pressures of two coupled sound sources but it remains a function of the complex acoustic impedance of the single coupled sound source being used.

When the same coupled sound source is used in both the ear canal and 2 cm^3 coupler SPL measurement, and it has a relatively high acoustic impedance, $|Z_s| >> |Z_e|$ and $|Z_s| >> |Z_c|$ Equation (B.2) reduces to:

$$ECLD = 20\lg\left|\frac{Z_e}{Z_c}\right| \text{dB} \quad \text{(B.3)}$$

Only in this case, is the ECLD a property of the ear alone, independent of the coupled sound source used in its measurement. Because this characteristic of the RECD is desirable and commonly assumed, this standard defines RECD only for this case.

Examples of situations where Equations (B.1), (B.2) and (B.3) apply are illustrated in Figure B.1, where computer simulations of the ECLD for an average adult ear (represented by the IEC 60318-4 occluded ear simulator) are shown and where:

- the dotted curve is the ECLD where Equation (B.1) applies. Here the ear canal SPL is produced by an ER-3 type insert earphone with its standard eartip (25 mm of 2 mm internal diameter tubing) while the coupler SPL is produced by the same insert earphone with its standard eartip connected to the 2 cm^3 coupler cavity by 18 mm of 3 mm internal diameter tubing (the connection described in IEC 60318-5 for a Behind the Ear (BTE) type hearing aid);
- the dashed curve is the ECLD where Equation (B.2) applies. Here both the ear canal and 2 cm^3 coupler cavity SPL measurements utilize the same BTE hearing aid with an earmould having 35 mm × 2 mm internal diameter tubing to its tip;
- the heavy solid curve is the ECLD where Equation (B.3) applies. Here both the ear canal and 2 cm^3 coupler cavity SPL measurements utilize a coupled sound source with a relatively high acoustic impedance, in this case an insert earphone with its standard eartip. In this case the ECLD is the RECD as defined in this standard.

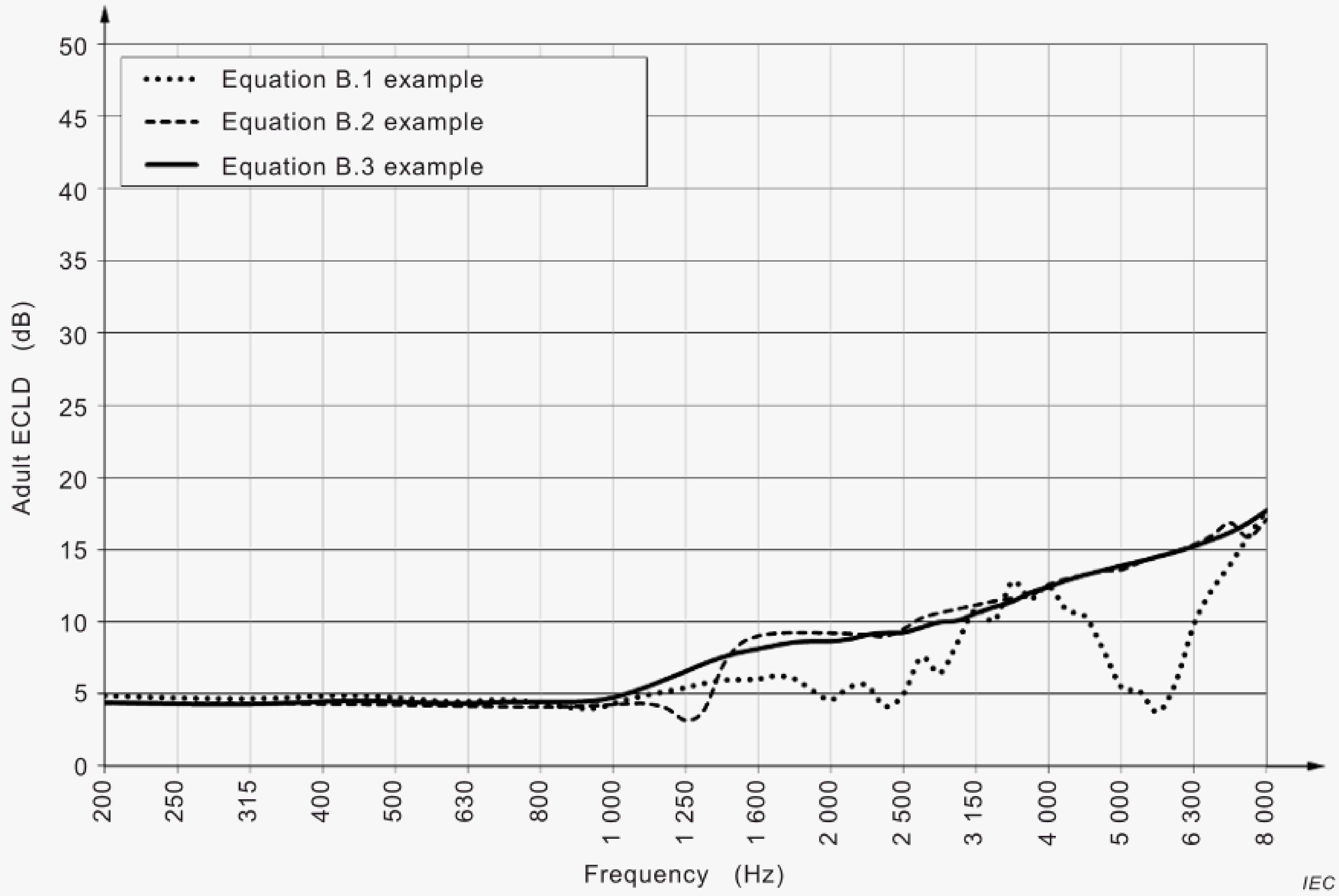


Figure B.1 – Computer-simulated ECLD for an average adult ear

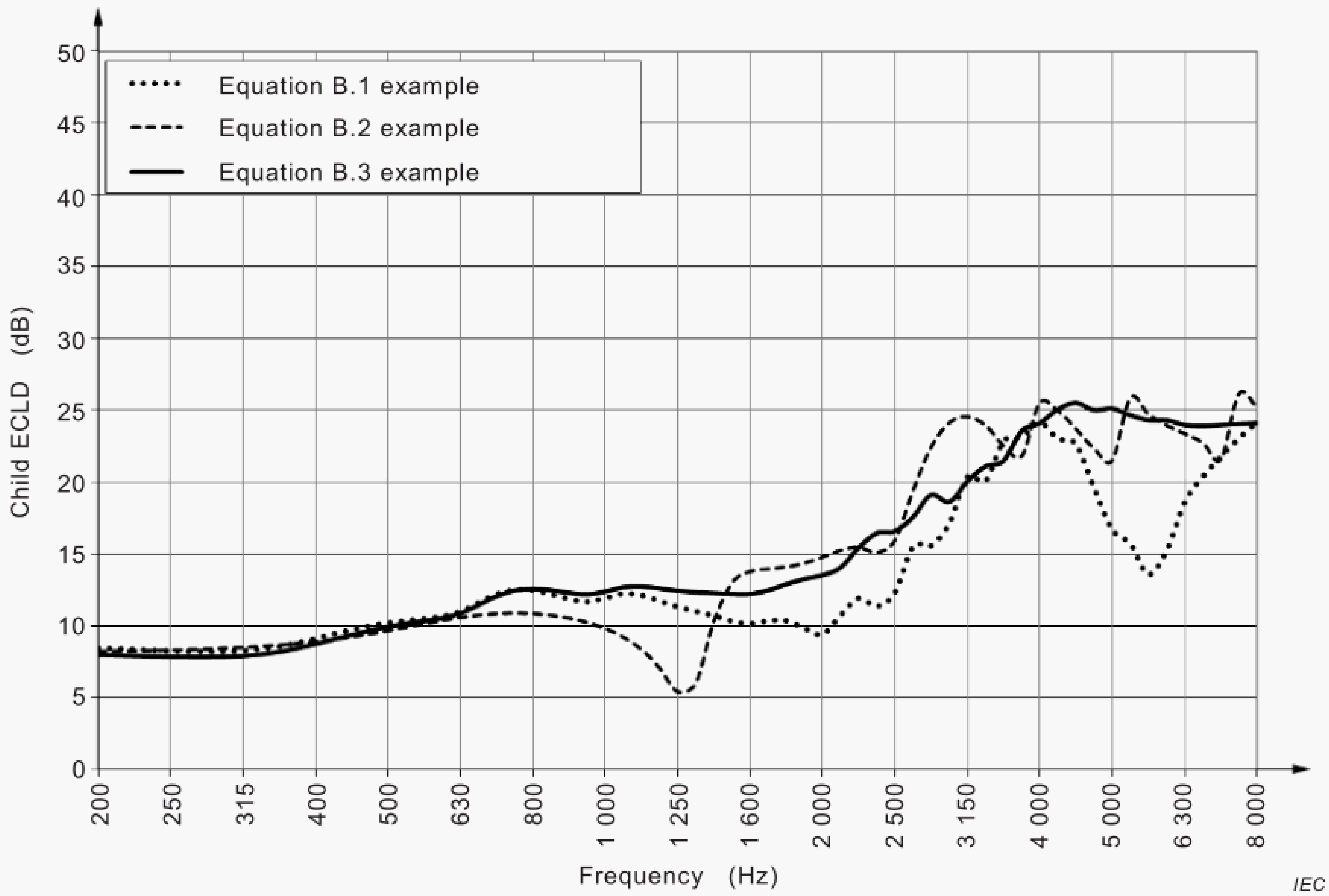


Figure B.2 – Computer-simulated ECLD for an average 3-month old child's ear

In Figure B.2, the model for the IEC 60318-4 type occluded-ear simulator is replaced by a model for a 3 month-old child's ear. Other conditions are as for Figure B.1.

B.3 Estimating ear canal SPL produced by a hearing aid

One of the clinical uses of RECD is to estimate the SPL that will be produced by a hearing aid in a ear canal from the SPL it produces in a 2 cm^3 coupler. The expression relating ear canal SPL to 2 cm^3 coupler SPL can be derived as:

$$L_{\mathrm{pe}} = L_{\mathrm{pc}} + 20\lg\left|\frac{Z_{\mathrm{e}}}{Z_{\mathrm{c}}}\right| dB + 20\lg\left|\frac{Z_{\mathrm{H}}+Z_{\mathrm{c}}}{Z_{\mathrm{H}}+Z_{\mathrm{e}}}\right| \mathrm{ECLD} = 20\lg\left|\frac{Z_{\mathrm{e}}}{Z_{\mathrm{c}}}\right| \mathrm{dB} + 20\lg\left|\frac{Z_{\mathrm{s}}+Z_{\mathrm{c}}}{Z_{\mathrm{s}}+Z_{\mathrm{e}}}\right| \mathrm{dB} \quad \text{(B.4)}$$

where:

L_{pe} is the SPL in the ear canal;

L_{pc} is the SPL in the 2 cm^3 coupler cavity;

Z_{e} is the complex acoustic impedance of the occluded ear;

Z_{c} is the complex acoustic impedance of the 2 cm^3 coupler cavity;

Z_{H} is the complex acoustic impedance of the hearing aid with its coupling to the occluded ear and 2 cm^3 coupler cavity.

When the RECD has been obtained using the method of this standard, Equation (B.4) becomes:

$$L_{\mathrm{pe}} = L_{\mathrm{pc}} + RECD + 20\lg\left|\frac{Z_{\mathrm{H}}+Z_{\mathrm{c}}}{Z_{\mathrm{H}}+Z_{\mathrm{e}}}\right| \mathrm{ECLD} = 20\lg\left|\frac{Z_{\mathrm{e}}}{Z_{\mathrm{c}}}\right| \mathrm{dB} + 20\lg\left|\frac{Z_{\mathrm{s}}+Z_{\mathrm{c}}}{Z_{\mathrm{s}}+Z_{\mathrm{e}}}\right| \mathrm{dB} \quad \text{(B.5)}$$

If the modulus of Z_{H} is not significantly larger than the moduli of Z_{c} and Z_{e}, which is the case for BTE type hearing aids with their earmoulds or thin tubes, Equation (B.5) applies and the estimated ear canal SPL depends on the complex acoustic impedance of the hearing aid as well as the RECD.

If $|Z_{\mathrm{H}}| >> |Z_{\mathrm{c}}|$ and $|Z_{\mathrm{H}}| >> |Z_{\mathrm{e}}|$, which is the case for hearing aids which have direct entry to the ear canal such as receiver in canal (RIC) and in the ear (ITE) types, Equation (B.5) becomes:

$$L_{\mathrm{pe}} = L_{\mathrm{pc}} + RECD\mathrm{ECLD} = 20\lg\left|\frac{Z_{\mathrm{e}}}{Z_{\mathrm{c}}}\right| \mathrm{dB} + 20\lg\left|\frac{Z_{\mathrm{s}}+Z_{\mathrm{c}}}{Z_{\mathrm{s}}+Z_{\mathrm{e}}}\right| \mathrm{dB} \quad \text{(B.6)}$$

The use of Equation (B.6) produces accurate estimates of ear canal SPL for RIC, ITE, in the canal (ITC) and completely in the canal (CIC) type hearing aids if the RECD has been derived using the methods of this standard. For BTE type hearing aids with their ear moulds or thin tubes, applying Equation (B.6) will produce errors in some frequency regions. The errors illustrated in the computer simulations which follow may not be observed in clinical practice and may not be clinically significant.

Figure B.3 is a computer simulation of the error in using Equation (B.6) to estimate the SPL produced by an ITE hearing aid (dotted curve) and by a BTE hearing aid with 30 mm of earmould tubing in an average adult ear if the RECD has been measured using an insert earphone and a standard eartip (heavy solid curve), and with 45 mm of earmould tubing if the RECD has been measured with this earmould (light solid curve). Also shown is the error if the method of this standard is not used (dashed curve). In this case the ECLD is derived using an earmould for the ear canal portion of the measurement but the 2 cm^3 coupler with the connection described in IEC 60318-5 for a BTE type hearing aid is used for the coupler portion. For the earmould the length of 2 mm internal diameter tubing from the tip of the earmould to the sound outlet of the hearing aid is 45 mm. The error for the ITE hearing aid is quite small because the modulus of its complex acoustic impedance is significantly higher than that of the average adult ear.

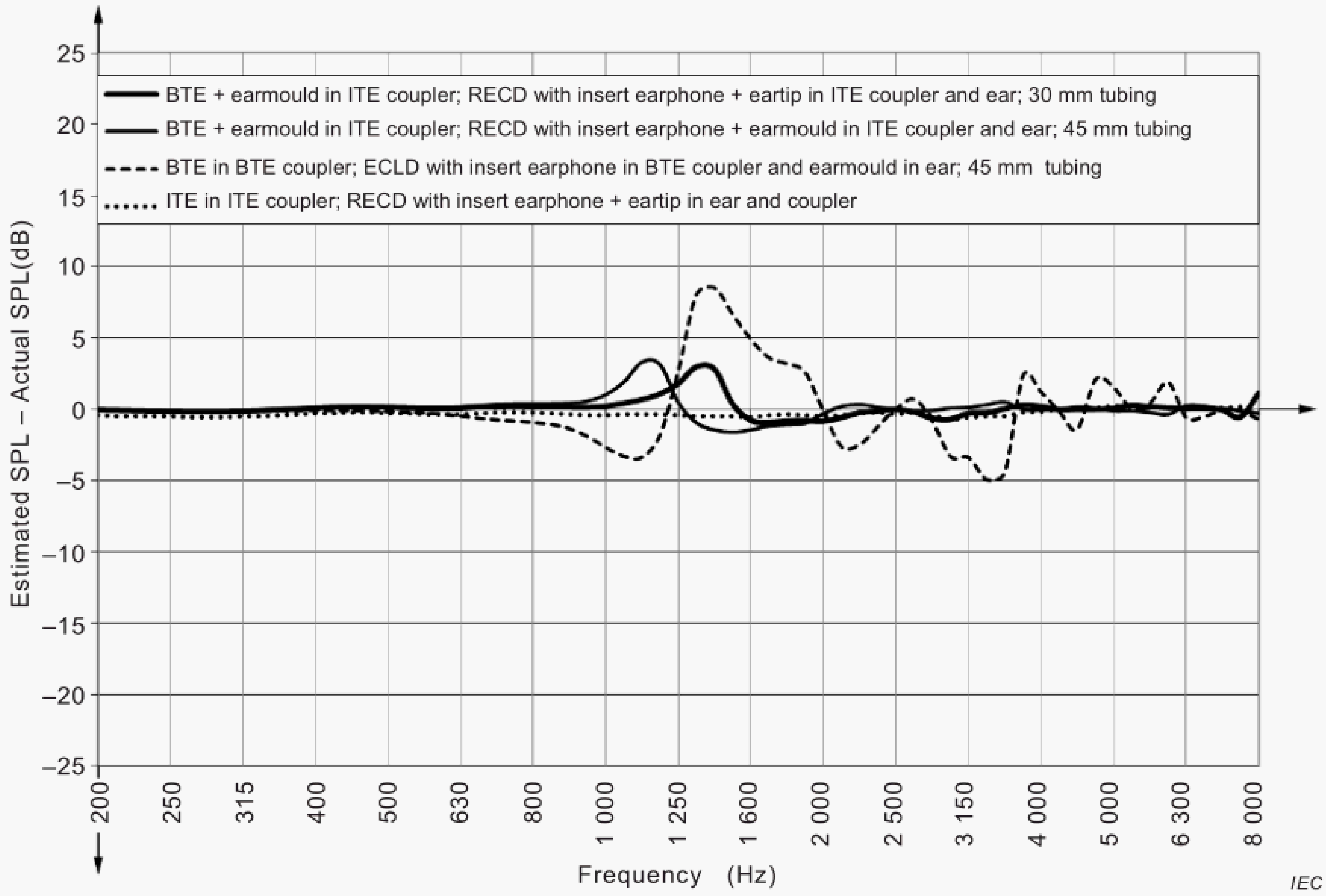


Figure B.3 – Computer-simulated error in estimating SPL in an average adult ear

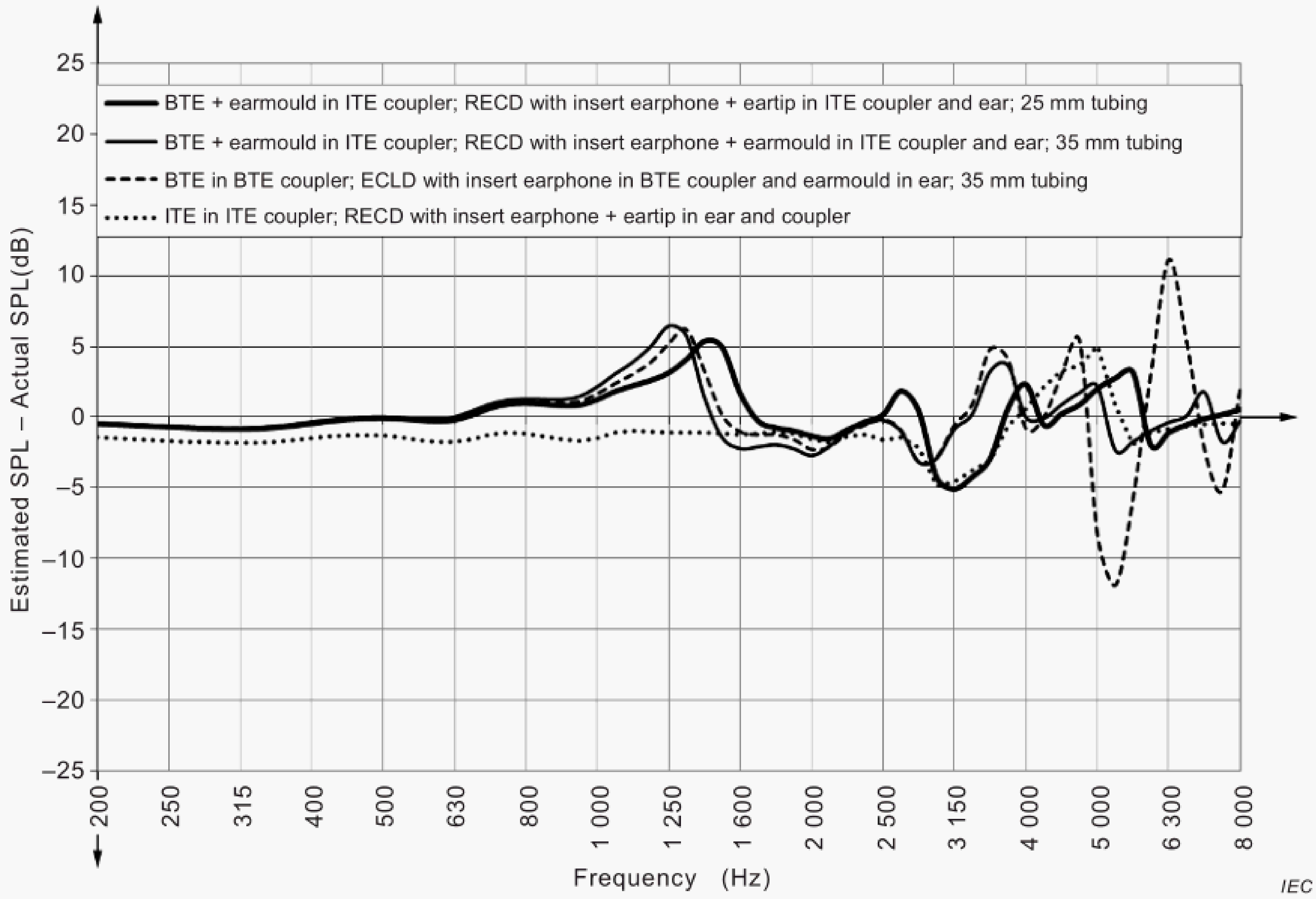


Figure B.4 – Computer-simulated error in estimating SPL in an average 3-month old child's ear

Figure B.4 is a computer simulation of the error in using Equation (B.6) to estimate the SPL produced by an ITE hearing aid (dotted curve) and by a BTE hearing aid with 25 mm of earmould tubing in the ear of a young child if the RECD has been measured using an insert earphone and a standard eartip (heavy solid curve), and with 35 mm of earmould tubing if the RECD has been measured with this earmould (light solid curve). Also shown is the error if the method of this standard is not used (dashed curve). In this case the ECLD is derived using an earmould for the ear canal portion of the measurement but the 2 cm^3 coupler with the connection described in IEC 60318-5 for a BTE type hearing aid is used for the coupler portion. For the earmould the length of 2 mm internal diameter tubing from the tip of the earmould to the sound outlet of the hearing aid is 35 mm. The error for the ITE hearing aid is larger than in the adult case because the modulus of its complex acoustic impedance is comparable to that of the child's ear at some frequencies.

B.4 Correcting an HL audiogram obtained with an insert earphone and a standard eartip

One of the clinical uses of RECD is to adjust hearing level (HL) measurements made on an individual ear using an audiometer with an insert earphone and a standard eartip calibrated for an average adult ear canal. For a given HL setting of the audiometer, the personal hearing level for the individual ear (PHL) is given by:

$$PHL = HL + L_{\mathrm{pPt}} - L_{\mathrm{pAt}}\mathrm{ECLD} = 20\lg\left|\frac{\mathrm{Z_e}}{\mathrm{Z_c}}\right|\mathrm{dB} + 20\lg\left|\frac{\mathrm{Z_s+Z_c}}{\mathrm{Z_s+Z_e}}\right|\mathrm{dB} \quad \text{(B.7)}$$

where:

L_{pPt} is the SPL produced in the individual ear by the insert earphone with its standard eartip;

L_{pAt} is the SPL produced in an average adult ear by the insert earphone with its standard eartip.

If the RECD has been obtained for this individual ear and for an average adult ear using an insert earphone with its standard eartip, Equation (B.7) can be rewritten as:

$$PHL = HL + PECD - AECD\mathrm{ECLD} = 20\lg\left|\frac{\mathrm{Z_e}}{\mathrm{Z_c}}\right|\mathrm{dB} + 20\lg\left|\frac{\mathrm{Z_s+Z_c}}{\mathrm{Z_s+Z_e}}\right|\mathrm{dB} \quad \text{(B.8)}$$

where:

$PECD$ is the personal RECD using an insert earphone and standard eartip for both the individual ear canal and 2 cm^3 coupler cavity SPL measurements;

$AECD$ is the average adult RECD using an insert earphone and standard eartip for both the ear canal and 2 cm^3 coupler cavity SPL measurements.

B.5 Correcting an HL audiogram obtained with an insert earphone and a custom earmould

In clinical practice working with children, it is not uncommon to replace the standard eartip on the insert earphone with the child's personal earmould. In this case, the adjustment to the HL audiogram can account for the complex acoustic impedance difference between the individual ear and that of an average adult as well as the difference in the coupled sound source used in the HL measurement from that for which the audiometer was calibrated. For a given HL setting of the audiometer, the personal hearing level (PHL) is given by:

$$PHL = HL + L_{\mathrm{pPm}} - L_{\mathrm{pAt}}\mathrm{ECLD} = 20\lg\left|\frac{\mathrm{Z_e}}{\mathrm{Z_c}}\right|\mathrm{dB} + 20\lg\left|\frac{\mathrm{Z_s+Z_c}}{\mathrm{Z_s+Z_e}}\right|\mathrm{dB} \quad \text{(B.9)}$$

where:

L_{pPm} is the SPL produced in the individual ear by the insert earphone with the personal earmould;

L_{pAt} is the SPL produced in an average adult ear by the insert earphone with its standard eartip.

Equation (B.9) can be rewritten as:

$$PHL = HL + L_{pPm} - L_{pCt} - AECD\mathrm{ECLD} = 20\lg\left|\frac{\mathrm{Z_e}}{\mathrm{Z_c}}\right|\mathrm{dB} + 20\lg\left|\frac{\mathrm{Z_s}+\mathrm{Z_c}}{\mathrm{Z_s}+\mathrm{Z_e}}\right|\mathrm{dB} \quad \text{(B.10)}$$

where:

$L_{pPm}L_{pCt}$ is the SPL produced in the 2 cm^3 coupler by the insert earphone with the standard eartip;

$AECD$ is the average adult RECD using an insert earphone and standard eartip for both the ear canal and 2 cm^3 coupler cavity SPL measurements.

Figure B.5 shows computer-simulated HL corrections for a 3 month old child's ear if an insert earphone with its standard tip (solid curve) and earmould with 35 mm of 2 mm internal diameter tubing (dashed curve) and 43 mm of 2 mm internal diameter tubing (dotted curve) have been used in the collection of HL data.

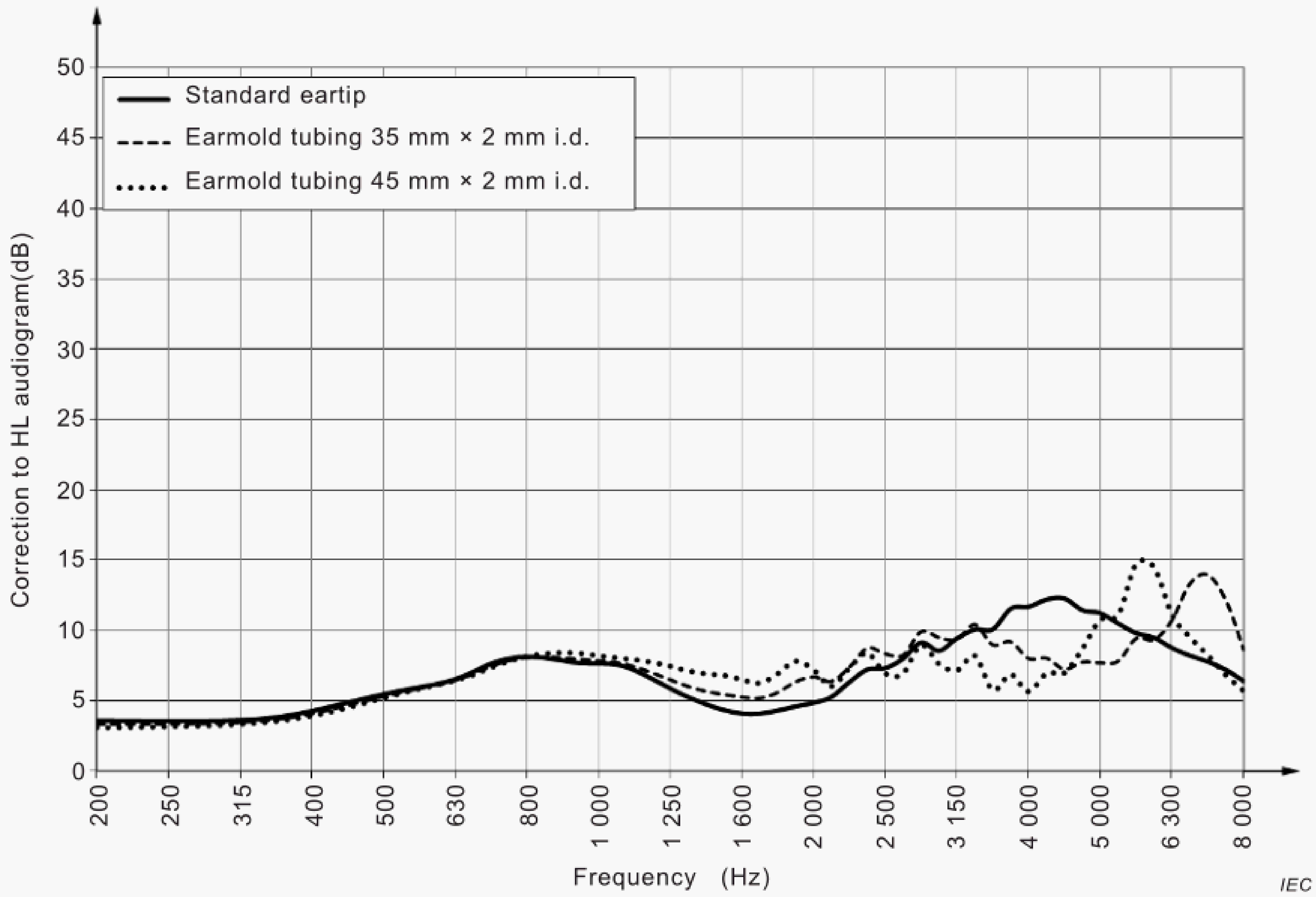


Figure B.5 – Computer-simulated HL correction for an average 3 month old child's ear

Annex C
(informative)

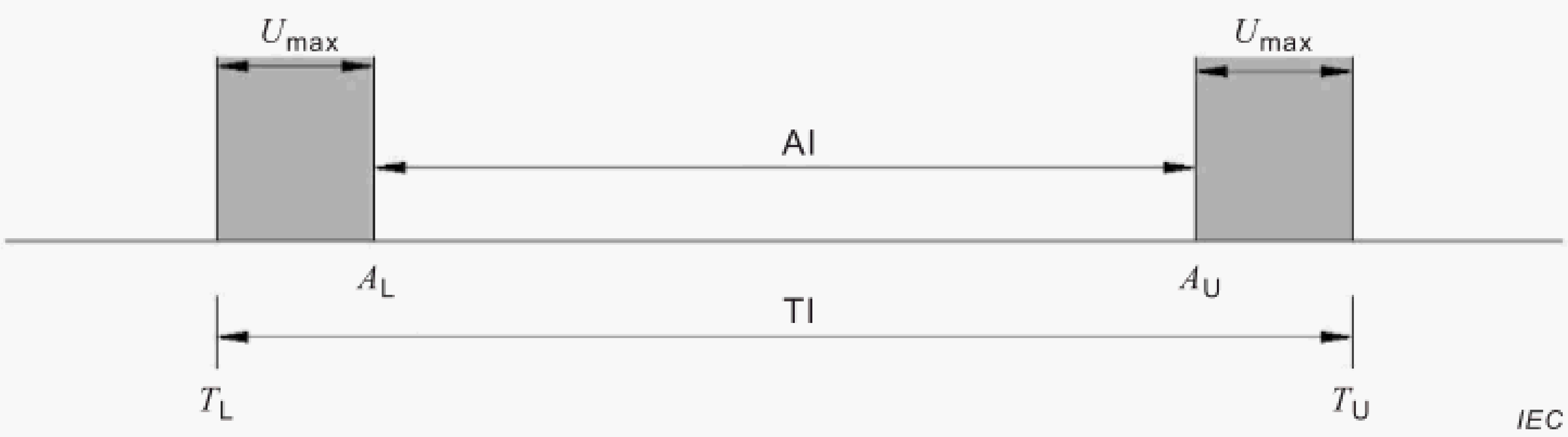
Relationship between tolerance interval, corresponding acceptance interval and the maximum permitted uncertainty of measurement

This standard uses adaptations of the guidelines from ISO/IEC Guide 98-4 (equivalent to guidance document JCGM 106 from the Joint Committee for Guides in Metrology), as the basis for demonstration of conformance of an instrument to the specifications given in this standard.

ISO/IEC Guide 98-4 describes guarded acceptance in terms of tolerance intervals, acceptance intervals and uncertainties of measurement.

To promote clarity for users and testing laboratories, tolerance limits around design goals are not explicitly stated, but can be determined if required from the specified acceptance limits for allowed deviations from a design goal and the corresponding specified maximum permitted uncertainty of measurement, by using the illustration in Figure C.1.

The limits of an acceptance interval are associated with the acceptance interval and not with the guard band for the maximum permitted uncertainty of measurement. Hence a measured deviation equal to a limit of an acceptance interval demonstrates conformance to a specification, provided also that the uncertainty of the measurement from the laboratory performing a test does not exceed the specified maximum permitted uncertainty.



Key

AI acceptance interval

TI tolerance interval

U_{max} guard band for the maximum permitted uncertainty of measurement for a 95 % coverage interval

A_L lower acceptance limit

A_U upper acceptance limit

T_L lower tolerance limit

T_U upper tolerance limit

Figure C.1 – Relationship between tolerance interval, corresponding acceptance interval and the maximum permitted uncertainty of measurement

Bibliography

IEC 60050-801, *International Electrotechnical Vocabulary – Chapter 801: Acoustics and electroacoustics*

IEC 60118-0, *Electroacoustics – Hearing aids – Part 0: Measurement of the performance characteristics of hearing aids*

IEC 60118-7, *Electroacoustics – Hearing aids – Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes*

IEC 60118-8, *Electroacoustics – Hearing aids – Part 8: Methods of measurement of performance characteristics of hearing aids under simulated in situ working conditions*

IEC 60118-15, *Electroacoustics – Hearing aids – Part 15: Methods for characterising signal processing in hearing aids with a speech-like signal*

IEC 60318-4, *Electroacoustics – Simulators of human head and ear – Part 4: Occluded-ear simulator for the measurement of earphones coupled to the ear by means of ear inserts*

ISO/IEC Guide 98-4, *Uncertainty of measurement – Part 4: Role of measurement uncertainty in conformity assessment*

JCGM 106, *Evaluation of measurement data – The role of measurement uncertainty in conformity assessment*

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