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Responsible committee: EPL/29 Electroacoustics

Interested committees:

Title: BS EN 60601-2-66 Medical electrical equipment

Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

PROJECT NUMBER: IEC 60601-2-66 ED4	
DATE OF CIRCULATION: 2024-07-05	CLOSING DATE FOR COMMENTS: 2024-09-27
SUPERSEDES DOCUMENTS: 29/1163/CD, 29/1167A/CC	

IEC TC 29 : ELECTROACOUSTICS		
SECRETARIAT: Denmark		SECRETARY: Ms Lise Aagesen
OF INTEREST TO THE FOLLOWING COMMITTEES:		HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED:		

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TITLE:

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems

NOTE FROM TC/SC OFFICERS:

At its meeting 2024-04-08/12 in Warsaw, Poland, IEC/TC 29 took the following decision, doc. 29/1173/DL refers:

DECISION 11

TC 29 decides to proceed with 1CD IEC 60601-2-66 "Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems" as a 2CD for a twelve-week commenting period with the following target dates:

CDV: 2025-01-31

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems

FOREWORD

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IEC 60601-2-66 has been prepared by IEC technical committee 29: Electroacoustics. It is an International Standard.

This fourth edition cancels and replaces the third edition published in October 2019.. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) Revised document structure for improved readability and referencing;
- b) New definitions added;
- c) The defined term FITTED OSPL90 is replaced by USE-CONDITION OUTPUT SATURATION LEVEL;

- d) USE-CONDITION GAIN80 added;
- e) Revision of clauses related to acoustic energy;
- f) Requirements for DIRECT-TO-CONSUMER HEARING AIDS added;
- g) Concept of SOUND DOSE in accordance with IEC 62368-1 as optional safety feature implemented;
- h) An informative Annex EE added to describe verification methods of SOUND DOSE monitoring and warning, SOUND DOSE limiting, and a calculation schema for output SOUND DOSE for a given gain characteristics.

The text of this International Standard is based on the following documents:

Draft	Report on voting
XX/XX/FDIS	XX/XX/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type*;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, the conjunction "or" is used as an "inclusive or" so a statement is true if any one or more of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in either Annex AA, or if general standard is referenced (clauses without the 201 prefix) to Annex A of the general standard .

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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

- reconfirmed,
- withdrawn, or
- revised.

499

INTRODUCTION

500 In 1998, the HEARING AID industry represented by the European hearing instrument
501 manufacturers association (EHIMA) attempted to establish a standard with the main purpose of
502 providing MANUFACTURERS with a guide to demonstrate conformity with the European Medical
503 Devices Directive 93/42/EEC.

504 The draft document prEN 50220 failed CENELEC vote and was published as "EHIMA standard"
505 in June 1998 with almost identical content. EHIMA concluded in 2009 that the requirements of
506 that standard were no longer up to date and an internationally accepted standard for HEARING
507 AID safety published by IEC or ISO to demonstrate compliance with regulatory requirements
508 should be produced.

509 This standard amends and supplements IEC 60601-1:2005 and
510 IEC 60601-1:2005/AMD1:2012/AMD2:2020, hereinafter referred to as the "general standard".

511 A general guidance and rationale for the requirements of this particular standard are given in
512 Annex AA. It is considered that knowledge of the reasons for these requirements will not only
513 facilitate the proper application of this particular standard but will, in due course, expedite any
514 revision necessitated by changes in clinical practice or as a result of developments in
515 technology. However, Annex AA does not form part of the requirements of this document.

516

517

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems****201.1 Scope, object and related standards**

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope*Replacement:*

This part of IEC 60601 applies to the BASIC SAFETY of HEARING AIDS and HEARING AID SYSTEMS, hereafter also referred to as ME EQUIPMENT or ME SYSTEM.

If a clause or subclause is specifically intended to be applicable to HEARING AIDS only, or to HEARING AID SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to HEARING AIDS and to HEARING AID SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of HEARING AIDS or HEARING AID SYSTEMS within the scope of this document are not covered by specific requirements in this document. This document does not specify any acoustical gain or output limits, as these depend on the individual needs of the user, which are determined by THE HEARING AID FITTING PROCESS. The HEARING AID FITTING PROCESS is not within the scope of this document. Requirements or limits related to the BASIC SAFETY of normal-hearing users relate to external references.

This document contains criteria for acoustical SAFETY for DIRECT-to-CONSUMER HEARING AIDS.

ACCESSORIES to HEARING AIDS in the HOME HEALTHCARE ENVIRONMENT (e.g. remote control units, audio streamers, battery chargers, power supplies) can be tested according to the applicable standard IEC 62368-1 or other applicable IEC safety standards. Alternatively, the general standard may be applied. HEARING AIDS do not have a MAINS PART intended for connection to AC SUPPLY MAINS. The connection to the SUPPLY MAINS of a HEARING AID SYSTEM is covered by power supply, charger or other types of ACCESSORIES.

ACCESSORIES with FUNCTIONAL CONNECTION to a HEARING AID may form a HEARING AID SYSTEM. HEARING AID related ACCESSORIES that are not physically connected to the HEARING AID during NORMAL USE are not considered to be APPLIED PART, because they do not directly contribute to the INTENDED USE of the HEARING AID.

Wireless programming interfaces are covered by the applicable standard IEC 62368-1 or other applicable IEC safety standards. Alternatively, the general standard may be applied.

Programming interfaces with wired connection to the HEARING AID are covered by the general standard.

NOTE Detachable parts of HEARING AIDS, even if supplied separately (e.g. ear hooks, domes, wax guards etc.), are not considered as ACCESSORIES, but as component parts.

¹ The general standard is IEC 60601-1 and IEC 60601-1:2005/AMD1:2012/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

This document does not apply to:

- cochlear implants or other implanted HEARING AIDS;
- bone conduction HEARING AIDS;
- educational HEARING AIDS (i.e. group HEARING AIDS, auditory trainers etc.);
- the application of a HEARING AID for the measurement of hearing levels; IEC 60645-1 applies;
- fixed installation audio-frequency induction-loop systems or their component parts, as described in IEC 60118-4 and IEC 62489-1;
- the sound generating function of a tinnitus masker.

This document does not address applicable testing for intentional RF radiation of wireless equipment (e.g. maximum radiated output power, modulation bandwidth, etc.).

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY requirements for HEARING AIDS and HEARING AID SYSTEMS as defined in 201.3.202 and 201.3.203.

201.1.3 * Collateral standards

Replacement:

Collateral standards address specific characteristics of the ME EQUIPMENT not fully addressed by this particular standard and shall apply together with this standard. This particular standard refers to those collateral standards listed in 201.2 Normative references.

IEC 60601-1-3, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. When evaluating compliance with IEC 60601-2-66, it is permissible to independently assess compliance with the collateral standards. The collateral standard being used to evaluate compliance shall explicitly be listed.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 and IEC 60601-1:2005/AMD1:2012/AMD2:2020 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Clauses or subclauses in this particular standard without the prefix "201" refer to the general standard, and the full text of the referenced clause in the general standard applies.

Clauses or subclauses in this particular standard with the prefix "201" refer to the corresponding clause or subclause in the general standard with changes to the text of the general standard (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard)

The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard, including all its underlying subclauses, is replaced completely by the text of this particular standard, unless any subclauses in the replacement reference the General Standard or an applicable collateral standard

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Where it is intended that any part of the general standard or applicable collateral standard, is not to be applied, a statement to that effect is given in this particular standard.

Clauses or subclauses where the full text of the referenced clause in the general standard applies where the text in the general standard further refers to other clauses/subclauses, then the corresponding clauses/subclauses in the particular standard take precedence for those references.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Replacement:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

IEC 60601-1-2:2014/AMD1:2020, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 62304:2006/AMD1:2015, *Medical device software – Software lifecycle processes*

IEC 60086-1:2021, *Primary batteries – Part 1: General*

IEC 60086-2:2021, *Primary batteries – Part 2: Physical and electrical specifications*

IEC 60086-4:2019, *Primary batteries – Part 4: Safety of lithium batteries*

IEC 60086-5:2021, *Primary batteries – Part 5: Safety of batteries with aqueous electrolyte*

IEC 60086-6:2020, *Primary batteries – Part 6: Guidance on environmental aspects*

IEC 61960-4:2020, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Secondary lithium cells and batteries for portable applications – Part 4: Coin secondary lithium cells, and batteries made from them*

IEC 62133-1:2017, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 1: Nickel systems*

IEC 62133-2:2017/AMD:2021, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems*

IEC 60118-0:2022, *Electroacoustics –Hearing aids – Part 0: Measurement of the performance characteristics of hearing aids*

IEC 60118-13:2019, *Electroacoustics – Hearing aids – Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices*

IEC 61032:1997, *Protection of persons and equipment by enclosures – Probes for verification*

IEC 62368-1:2023, *Audio/video, information and communication technology equipment –Part 1: Safety requirements*

ISO 10993-1:2018, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*

ISO 14971: 2019, *Medical devices – Application of risk management to medical devices*

IEC 60068-2-2: 2007, *Environmental testing – Part 2-2: Tests – Test B: Dry heat*

IEC 60529:1989/AMD1:1999/AMD2:2013 *Degrees of protection provided by enclosures (IP Code)*

ISO 780, *Packaging – Distribution packaging — Graphical symbols for handling and storage of packages*

ISO 3864-1: 2011, *Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings*

ISO 7000, *Graphical symbols for use on equipment*

ISO 7010: 2019, *Graphical symbols – Safety colours and safety signs – Registered safety signs*

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

201.3 Terminology and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 and IEC 60601-1:2005/AMD1:2012/AMD2:2020 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

NOTE An index of defined terms is found beginning on page 98.

201.3.4

ACCOMPANYING DOCUMENT

Addition:

Note 1 to entry labels affixed to containers and wrapping of a ME EQUIPMENT is considered an ACCOMPANYING DOCUMENT (reference: ISO 13485)

201.3.73

OPERATOR

Addition:

NOTE 1 to entry: Usually equals to PATIENT for HEARING AIDS in a home healthcare environment.

201.3.76

PATIENT

Replacement:

Person for whom the HEARING AID or HEARING AID SYSTEM is intended.

NOTE 1 to entry: In this particular standard and in applying the requirements of the general standard, the term patient has the meaning explained in the second paragraph of 4.1 of the general standard. The patient is also usually the operator.

NOTE 2 to entry: The term patient is being used in this document in line with the general terminology in the medical product field. It is, however, understood that the user of a hearing aids is typically not an ill person but someone healthy with a hearing impairment in a home healthcare environment.

201.3.113

SERVICE PERSONNEL

Replacement:

Individuals or entity that assemble, maintain or repair HEARING AIDS or HEARING AID SYSTEMS

201.3.132

TYPE B APPLIED PART

Replacement:

APPLIED PART complying with the specified requirements of this particular standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT

Addition:

201.3.201

HEARING AID MEDICAL FUNCTION

MEDICAL FUNCTION

The function of delivering acoustical energy to the ear.

201.3.202

HEARING AID FITTING

FITTING

For the purpose of BASIC SAFETY, HEARING AID FITTING is the PROCESS where the HEARING AID along with its parameters, including UC-GAIN80 and UC-OSSPL, is configured according to the individual user needs while minimizing the risk of further permanent threshold shift (PTS) assuming long-term use conditions.

201.3.203**HEARING AID****ME EQUIPMENT**

EQUIPMENT which picks up sound and delivers PROCESSED sound to the ear canal through air-conduction for serving its INTENDED USE to alleviate a hearing deficit.

NOTE 1 to entry: A hearing aid includes all detachable parts that are essential for the performance of its intended use.

201.3.204**HEARING AID SYSTEM****ME SYSTEM**

Combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is a HEARING AID to be inter-connected by specified FUNCTIONAL CONNECTIONS while performing its MEDICAL FUNCTION.

201.3.205**HEARING AID PROFESSIONAL****HAP**

Audiological competent person who professionally assess hearing, selects, fits and delivers HEARING AID SYSTEMS and rehabilitation services to persons with hearing impairment.

201.3.206**PROFESSIONALLY PROVIDED HEARING AID**

A HEARING AID which is provided by a HEARING AID PROFESSIONAL in accordance with ISO 21388 including a HEARING AID FITTING.

201.3.207**DIRECT-TO-CONSUMER HEARING AID**

A HEARING AID which is delivered to the user without the individual assessment of a hearing aid professional.

201.3.208**SELF-FITTING HEARING AID**

A HEARING AID with means and procedures implemented in the HEARING AID and/or its ACCESSORIES (e.g. smartphone app), for performing the hearing aid fitting by the user of the HEARING AID.

201.3.209**PRE-SET HEARING AID****READY-TO-USE HEARING AID**

A HEARING AID with a fixed setting, or multiple pre-defined sets of HEARING AID parameters (listening programs).

Note: If a pre-set hearing aid is selected and provided by a hearing aid professional then it referred to as a professionally provided pre-set hearing aid; otherwise it is referred to as direct-to-consumer pre-set hearing aid.

201.3.210**HEARING AID FITTING SOFTWARE**

Software to control and visualize the setting of HEARING AID parameters.

201.3.211**HEARING AID FITTING ALGORITHM**

Algorithm or software to convert hearing loss data into parameter settings of a HEARING AID.

NOTE The Software described in 201.3.210 and 201.2.211 is often combined.

201.3.212

MAXIMUM OUTPUT SOUND PRESSURE LEVEL FOR 90 dB input SPL

MAXIMUM OSPL₉₀

Maximum value of the output response of the HEARING AID when measured with full-on setting and 90 dB input SPL, as defined in IEC 60118-0

201.3.213

USE-CONDITION

Condition of the HEARING AID as used by the hearing impaired in PRE-SET or FITTED condition.

NOTE 1 to entry: the UC-GAIN₈₀ and UC-OSSPL stand in lieu of all HEARING AID parameters in PRE-SET or FITTED condition and should not be understood as FITTING targets.

NOTE 2 to entry: For recording and verification measurements, user-controlled volume control is set to maximum position.

NOTE 3 to entry: In case of multiple user-selectable hearing-programs, UC-GAIN₈₀ and UC-OSSPL apply to each program.

NOTE 4 to entry: For verification measurements all adaptive parameters (noise-, feedback-suppression, etc.) are switched off.

201.3.214

USE-CONDITION OUTPUT SATURATION SOUND PRESSURE LEVEL²

UC-OSSPL

Saturation output response of a HEARING AID when measured in use-condition.

NOTE 1 to entry: This can be measured by means of frequency responses recorded at input sound pressure levels increasing in steps of 3 dB. If an increase of input sound pressure level by 3 dB results in an increase of output sound pressure level by less than 1 dB, the UC-OSSPL is reached.

201.3.215

USE-CONDITION GAIN AT 80 dB INPUT SPL²

UC-GAIN₈₀

Output response minus 80 dB of a HEARING AID when measured at 80 dB input SPL in USE-CONDITION.

201.3.216

SOUND PRESSURE LEVEL

SPL

L_p

Ten times the logarithm to the base 10 of the ratio of the square of the root-mean-square of the sound pressure in the time domain, p , to the square of the reference value, p_0 , expressed in decibels

$$L_p = 10 \log_{10} \frac{\bar{p}^2}{p_0^2} \text{ dB}$$

where the reference value, p_0 , is 20 μPa

NOTE 1 to entry: p^2 is understood to denote the square of a frequency-weighted, frequency-band-limited or time-weighted sound pressure.

If specific frequency and time weightings as specified in IEC 61672-1 and/or specific frequency bands are applied, this should be indicated by appropriate subscripts; e.g. $L_{p,AF}$ denotes the A-weighted SOUND PRESSURE LEVEL with time weighting F.

² For simplified communication purposes a subset of the response curve (numerical data) may be used, for example to evaluate frequency specific values, HFA value, or maximum value

NOTE 2 to entry: This definition is technically in accordance with ISO 80000-8:2020, 8-14.

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

NOTE 4 to entry: Any SOUND PRESSURE LEVEL specified in this document is measured in decibels (dB) as described in IEC 60118-0 by using a coupler according to IEC 60318-5.

[SOURCE: ISO/TR 25417:2007, 2.2. modified – The abbreviated term "SPL" has been added, as well as Notes 3 and 4 to entry.]

201.3.217

A-weighted SOUND EXPOSURE $E_{A,T}$

SOUND DOSE

Integral over the effective duration of the squared instantaneous A-weighted SOUND PRESSURE

$$E_{A,T} = \int_0^{T_e} [p_A(t)]^2 dt$$

where, p_A is the instantaneous A-weighted sound pressure

T_e is the effective duration

$E_{A,T}$ is measured in Pa²h

NOTE: IEC 62368-1, clause 10.6 specifies CSD 100 % as = 80 dB / 40 h which corresponds to SOUND EXPOSURE of 1.6 Pa²h (one week rolling estimate).

201.3.218

EQUIVALENT A-WEIGHTED CONTINUOUS SOUND PRESSURE LEVEL L_{Aeq,T_e}

The constant SOUND PRESSURE LEVEL that would result in the same total sound energy as the fluctuating SOUND PRESSURE LEVEL being produced over a given period of time.

The level in decibels given by the formula

$$L_{Aeq,T_e} = 10 \log_{10} \frac{\frac{1}{T_e} \int_0^{T_e} [p_A(t)]^2 dt}{p_0^2} \text{ dB}$$

where,

p_A is the instantaneous A-weighted SOUND PRESSURE

$p_0 = 20 \text{ } \mu\text{Pa}$

T_e is the effective duration

NOTE 1: See IEC Electropedia, IEV ref 801-22-16

NOTE 2: IEC 62368-1, clause 10.6 specifies $L_{Aeq,40h} = 80 \text{ dB}$ as CSD 100 % (rolling 40 h per week)

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Replacement:

Unless otherwise specified, the requirements of this document shall apply in NORMAL USE and reasonably foreseeable misuse.

When applying this document to HEARING AID or HEARING AID SYSTEMS, the definitions and requirements that use the term PATIENT shall be considered as applying to the person for whom the HEARING AID or HEARING AID SYSTEMS is intended.

4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

4.2.1 Introduction to RISK MANAGEMENT

4.2.2 General requirement for RISK MANAGEMENT

4.2.3 Evaluating RISK

4.2.3.1 HAZARDS identified in the IEC 60601- series

4.2.3.2 HAZARDS not identified in the IEC 60601-series

201.4.3 ESSENTIAL PERFORMANCE

Addition:

See Annex CC.

4.4 * EXPECTED SERVICE LIFE

4.5 * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

201.4.6 ME EQUIPMENT or ME SYSTEMS parts that contact the PATIENT [does not apply]

Subclause 4.6 of the general standard does not apply.

4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

4.8 * Components of ME EQUIPMENT

4.9 * Use of COMPONENTS WITH HIGH INTEGRITY CHARACTERISTICS in ME EQUIPMENT

201.4.10 Power supply

Replacement:

HEARING AIDS in NORMAL USE are INTERNALLY POWERED by means of primary or rechargeable batteries.

If a HEARING AID is specified for connection to a separate power source, the separate power source and relevant ACCESSORIES to the HEARING AID shall be in compliance with the relevant standard IEC 62368-1 or other applicable IEC safety standards.

201.4.11 Power input [does not apply]

Subclause 4.11 of the general standard does not apply.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

5.1 * TYPE TESTS

201.5.2 Number of samples

Replacement:

TYPE TESTS are performed on a representative sample of the item being tested. If multiple products are under consideration, which have a similar mechanical and electrical architecture, then an engineering analysis by the MANUFACTURER may justify a single representative sample for a family of products.

201.5.3 Ambient temperature, humidity, atmospheric pressure

Replacement:

After the HEARING AID or HEARING AID SYSTEM to be tested has been set up for NORMAL USE, tests are performed within the range of environmental conditions indicated in the technical description, as specified by the MANUFACTURER.

201.5.4 Other conditions

Addition:

aa) Inventory stocking conditions are specified by the MANUFACTURER.

bb) HEARING AID transport conditions are specified by the MANUFACTURER.

201.5.5 Supply voltages, type of current, nature of supply, frequency

Replacement:

Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations shall be taken into account.

HEARING AID and HEARING AID SYSTEMS designed for more than one RATED voltage shall be tested in conditions related to the least favourable voltage and nature of supply.

HEARING AIDS for which alternative ACCESSORIES or detachable parts can be connected as specified in the ACCOMPANYING DOCUMENTS shall be tested with those ACCESSORIES or detachable parts that result in the least favourable conditions.

HEARING AIDS in NORMAL USE are INTERNALLY POWERED. If a HEARING AID is designed to receive power from a separate power supply during INTENDED USE, it shall be connected to such a power supply. See 201.8.2.1

5.6 Repairs and modifications

201.5.7 Humidity preconditioning treatment

Replacement:

Where climatic conditions could influence the safety of a HEARING AID or HEARING AID SYSTEM or its parts, it shall be subjected to a humidity preconditioning treatment prior to the tests of 201.8.7.4.

HEARING AID and HEARING AID SYSTEMS or their parts shall be set up completely (or where necessary partially). Covers used during transport and storage shall be detached.

Parts that can be detached without the use of tools shall be detached, but tested simultaneously with the major part.

ACCESS COVERS that can be opened or detached without the use of tools shall be opened and detached.

The humidity preconditioning treatment shall be performed in a humidity cabinet containing air with a relative humidity of $93 \% \pm 3 \%$ where the ME EQUIPMENT or its parts under test are located. The humidity conditions at other locations in the chamber may vary by $\pm 6 \%$. The

temperature of the air in the cabinet, at all places where HEARING AIDS and HEARING AID SYSTEMS can be located, shall be maintained within 2 °C of any convenient value T in the range of +20 °C to +30 °C. Before being placed in the humidity cabinet, HEARING AIDS and HEARING AID SYSTEMS are brought to a temperature between T and $T + 4$ °C, and kept at this temperature for at least 4 h before the humidity treatment starts.

Keep HEARING AIDS and HEARING AID SYSTEMS and their parts, where the ENCLOSURE is classified as IPX0, in the humidity cabinet for at least 48 h.

Keep HEARING AIDS and HEARING AID SYSTEMS and its parts, where the ENCLOSURE is designed to provide higher ingress protection against liquids, in the humidity cabinet for 168 h.

5.8 Sequence of tests

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

201.5.9.1 * APPLIED PARTS

Replacement:

The HEARING AID is a TYPE B APPLIED PART. Parts that come into contact with the PATIENT while the HEARING AID performs its MEDICAL FUNCTION of delivering acoustic energy to the ear are also TYPE B APPLIED PARTS. Examples for these parts are ear moulds, acoustic coupling tubing, cables for Receiver-in-the-Canal instruments.

Hand-held or body worn devices, not conveying acoustic energy are not considered as applied parts. Examples are User Remote Controls, FM-Receivers, Wireless Intermediate Devices. See also Table 201.101.

Since the HEARING AID and APPLIED PART is physically identical, the HEARING AID specific information in the ACCOMPANYING DOCUMENTS apply, APPLIED PART specific marking with symbol IEC 60417-5840 is not required.

201.5.9.2 ACCESSIBLE PARTS

201.5.9.2.1 Test finger

Amendment:

The tests as described in the general standard are performed with the small finger probe as shown in Figure 13 of IEC 61032.

201.5.9.2.2 Test hook [does not apply]

Sub-clause 5.9.2.2 of the general standard does not apply to HEARING AIDS

201.5.9.2.3 Actuating mechanism [does not apply]

Sub-clause 5.9.2.3 of the general standard does not apply to HEARING AIDS

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

6.1 General

201.6.2 Protection against electric shock

Replacement:

HEARING AIDS are INTERNALLY POWERED, but may have connections to mains supplied equipment. The insulation between the SUPPLY MAINS and the HEARING AID shall be provided within the power supply, charger or other type of ACCESSORY. ACCESSORIES to HEARING AIDS shall be in compliance to IEC60601-1 or IEC 62368-1 or other applicable IEC safety standards.

The HEARING AID is classified a TYPE B APPLIED PART.

201.6.3 Protection against harmful ingress of water or particulate matter

Replacement:

See 7.2.9 and 201.11.6.5.

201.6.4 Method(s) of sterilization [does not apply]

Sub-clause 6.4 of the general standard does not apply to HEARING AIDS

6.5 Suitability for use in an OXYGEN RICH ATMOSPHERE

201.6.6 Mode of operation

Replacement:

HEARING AIDS are classified for CONTINUOUS OPERATION.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.1 General

201.7.1.1 USABILITY of the identification, marking and documents

Replacement:

The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISK of poor USABILITY associated with the design of the HEARING AIDS identification, marking and documents.

The USABILITY of the identification, marking and ACCOMPANYING DOCUMENTS intended for the PATIENT shall be evaluated based on a PATIENT profile that includes basic school education.

HEARING AIDS should be designed to be simple to use and not require reference to complex ACCOMPANYING DOCUMENTS.

Compliance shall be checked by inspection of the results of the RISK MANAGEMENT PROCESS.

201.7.1.2 Legibility of markings

Replacement:

The markings required by 201.7.2 and 201.7.3 shall be CLEARLY LEGIBLE under the following conditions:

- safety signs and identification, on the HEARING AID except serial number, shall be CLEARLY LEGIBLE when it is placed in the hand of the PATIENT;
- the serial number and any other markings shall be legible utilizing an optical aid with 3-times magnification, if necessary.

Compliance for clear legibility is checked by the following test:

- *The ME EQUIPMENT or its part is positioned so that the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 20 cm to 45 cm.*
- *The ambient illumination is approximately 500 lx.*
- *The reader has a visual acuity, corrected if necessary, of:*
 - *0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20);*
 - *is able to read N6 of the Jaeger test card;*
 - *in normal room lighting conditions (approximately 500 lx).*

The reader correctly reads the marking from the viewpoint.

201.7.1.3 Durability of markings

Addition:

Markings that are engraved or moulded is considered durable by design, hence no testing is needed.

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

Replacement:

The markings as indicated in 201.7.2.2 shall be affixed or shall be recorded in the accompanying documents as described in 201.7.2.2.

All other markings as required in 201.7.2 shall be recorded in the accompanying documents.

201.7.2.2 Identification

Replacement:

HEARING AIDS shall be marked on the outside with:

- the name, tradename or trademark of the MANUFACTURER;
- a MODEL OR TYPE REFERENCE.

HEARING AIDS shall be marked visibly on the outside or other user accessible location:

- identification of right and left HEARING AID unless absence of this marking does not present an unacceptable RISK. Right is defined by the colour red. Left is defined by the colour blue;
- serial number.

In case of HEARING AIDS worn in the ear or other small HEARING AIDS, the MODEL OR TYPE REFERENCE may be recorded in the ACCOMPANYING DOCUMENTS provided that the serial number of the HEARING AID is also recorded in the ACCOMPANYING DOCUMENTS.

In case of custom made HEARING AIDS worn in the ear, the serial number shall be recorded in the individual data of the ACCOMPANYING DOCUMENTS.

HEARING AIDS shall be marked visibly on the outside or other user accessible location or on the package with:

- the year of manufacture.

1027 The serial number, lot or batch identifier, and the year of manufacture may be provided in a
1028 human readable code or through automatic identification technology such as barcodes or RFID
1029 (radio-frequency identification).

1030 NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use
1031 by date.

1032 **201.7.2.3 Consult ACCOMPANYING DOCUMENTS** [does not apply]

1033 Subclause 7.2.3 of the general standard does not apply.

1034 **7.2.4 * ACCESSORIES**

1035 **201.7.2.5 ME EQUIPMENT intended to receive power from other equipment** [does not
1036 apply]

1037 Subclause 7.2.5 of the general standard does not apply.

1038 **201.7.2.6 Connection to the SUPPLY MAINS**

1039 *Replacement:*

1040 HEARING AIDS are INTERNALLY POWERED but may have connections to mains supplied equipment,
1041 for example, power supply, charger, or other types of ACCESSORIES.

1042 The markings on such ACCESSORIES shall comply with IEC 62368-1 or other applicable IEC
1043 safety standards.

1044 **201.7.2.7 Electrical input power from the SUPPLY MAINS**

1045 *Replacement:*

1046 See 201.7.2.6

1047 **201.7.2.8 Output connectors** [does not apply]

1048 Subclause 7.2.8 of the general standard does not apply.

1049 **201.7.2.9 IP classification**

1050 *Addition:*

1051
1052 Symbol for IP classification may be marked in ACCOMPANYING DOCUMENTS instead of marking on
1053 HEARING AID itself.

1054 **201.7.2.10 APPLIED PARTS** [does not apply]

1055 Subclause 7.2.10 of the general standard does not apply.

1056 **201.7.2.11 Mode of operation** [does not apply]

1057 Subclause 7.2.11 of the general standard does not apply

1058 **201.7.2.12 Fuses** [does not apply]

1059 Subclause 7.2.12 of the general standard does not apply

1060 **201.7.2.13 Physiological effects (SAFETY SIGNS and warning statements)** [does not
1061 apply]

1062 Subclause 7.2.13 of the general standard does not apply

1063 **201.7.2.14 HIGH VOLTAGE TERMINAL DEVICES** [does not apply]

1064 Subclause 7.2.14 of the general standard does not apply

1065 **201.7.2.15 Cooling conditions** [does not apply]

1066 Subclause 7.2.15 of the general standard does not apply

1067 **201.7.2.16 Mechanical stability** [does not apply]

1068 Subclause 7.2.16 of the general standard does not apply

1069 **201.7.2.17 Protective packaging**

1070 *Replacement:*

1071 If special handling measures have to be taken during transport or storage, the packaging shall
1072 be marked accordingly.

1073 **201.7.2.18 External pressure source** [does not apply]

1074 Subclause 7.2.18 of the general standard does not apply

1075 **201.7.2.19 FUNCTIONAL EARTH TERMINALS** [does not apply]

1076 Subclause 7.2.19 of the general standard does not apply

1077 **201.7.2.20 Removable protective means** [does not apply]

1078 Subclause 7.2.20 of the general standard does not apply

1079 **201.7.2.21 Mass of MOBILE ME EQUIPMENT** [does not apply]

1080 Subclause 7.2.21 of the general standard does not apply

1081 **201.7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts** (see also
1082 Table C.2)

1083 Subclause 7.3 of the general standard does not apply, except for 7.3.3.

1084 **201.7.3.3 Batteries**

1085 *Replacement:*

1086 Correct insertion of exchangeable batteries shall be indicated, for example by polarity sign, or
1087 battery pictogram.

1088 **201.7.4 Marking of controls and instruments**

1089 **201.7.4.1 Power switches**

1090 *Replacement:*

1091 The requirements of this sub clause are included in 201.7.4.2

1092 **201.7.4.2 Control devices**

1093 *Replacement:*

1094 HEARING AID user controlled switches with two or more positions shall be marked (e.g. M for
1095 microphone position, T for inductive signal pickup, O for off).

1096 Controls used for HEARING AID FITTING shall indicate the level or degree of function.

1097 **201.7.4.3 Units of measurement** [does not apply]

1098 Subclause 7.4.3 of the general standard does not apply

1099 **201.7.5 SAFETY SIGNS** [does not apply]

1100 Subclause 7.5 of the general standard does not apply

1101 **201.7.6 Symbols** [does not apply]

1102 Subclause 7.6 of the general standard does not apply

1103 **201.7.7 Colours of the insulation of conductors** [does not apply]

1104 Subclause 7.7 of the general standard does not apply

1105 **201.7.8 * Indicator lights and controls**

1106 Subclause 7.8 of the general standard does not apply, except for 7.8.1

1107 **201.7.8.1 Colours of indicator lights**

1108 *Replacement:*

1109 The colours of indicator lights and their meanings shall be stated in the instructions for use.

1110 *Compliance with the requirements is checked by inspection.*

1111 **201.7.9 ACCOMPANYING DOCUMENTS**

1112 **201.7.9.1 General**

1113 *Replacement:*

1114 HEARING AIDS shall be accompanied by documents containing at least the instructions for use
1115 and a technical description. The technical description may be included in the same document
1116 as the instructions for use. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the
1117 HEARING AID.

1118 The ACCOMPANYING DOCUMENTS shall identify the HEARING AID by including, as applicable, the
1119 following:

- 1120 – name or trade-name of the MANUFACTURER and contact information to which the PATIENT can
1121 refer;
- 1122 – MODEL OR TYPE REFERENCE;
- 1123 – for HEARING AIDS capable of a MAXIMUM OSPL90 exceeding 132 dB SPL: warning to the
1124 HEARING AID PROFESSIONAL fitting the HEARING AID that there may be a RISK of impairing the
1125 remaining hearing of the PATIENT.

1126 The format of the ACCOMPANYING DOCUMENTS whether being printed or provided electronically,
1127 e.g. electronic file format that can be publicly downloaded, shall follow local legislations.

1128 If the ACCOMPANYING DOCUMENTS are provided electronically, the USABILITY ENGINEERING PROCESS shall
1129 include consideration of which information also needs to be provided as hard copy.