

INTERNATIONAL STANDARD



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



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INTERNATIONAL STANDARD



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

INTERNATIONAL
ELECTROTECHNICAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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

This third edition cancels and replaces the second edition published in 2015. It constitutes a technical revision.

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

- a) revision of the definition about ESSENTIAL PERFORMANCE;
- b) revision of the application of IEC 60601-1-2:2014 for electromagnetic disturbances;
- c) correction of the used voltage for HEARING AIDS from 1,6 V to 4,5 V;
- d) correction of the drop test level from 1,5 m to 1,0 m;
- e) correction of the wording of IEC 60601-2-66:2015.

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

FDIS	Report on voting
29/1023/FDIS	29/1030/RVD

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

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

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 conjunctive "or" is used as an "inclusive or" so a statement is true if any combination 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 Annex AA.

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 "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

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

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

~~This resulting IEC standard amends and supplements IEC 60601-1 (third edition, 2005): Medical electrical equipment – Part 1: General requirements for safety and essential performance, hereinafter referred to as 'the general standard'.~~

~~Figures in square brackets refer to the Bibliography.~~

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

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

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-66: Particular requirements for the basic safety and essential performance of hearing ~~instruments~~ aids and hearing ~~instrument~~ 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 ~~INSTRUMENTS~~ AID~~S~~ and HEARING ~~INSTRUMENT~~ 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 ~~INSTRUMENTS~~ AID~~S~~ only, or to HEARING ~~INSTRUMENT~~ 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 ~~INSTRUMENTS~~ AID~~S~~ and to HEARING ~~INSTRUMENT~~ AID SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of HEARING ~~INSTRUMENTS~~ AID~~S~~ or HEARING ~~INSTRUMENT~~ AID SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 201.7.9.2 and 201.9.6.

NOTE See also ~~201.4.2. (RISK MANAGEMENT)~~ 4.2 of the general standard.

ACCESSORIES to HEARING ~~INSTRUMENTS~~ AID~~S~~ in the HOME HEALTHCARE ENVIRONMENT (e.g. remote control units, audio streamers, battery chargers, power supplies) ~~are covered by the most can be tested according to the applicable standard, IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards. Alternatively, the general standard may be applied. HEARING~~ ~~INSTRUMENTS~~ AID~~S~~ do not have a MAINS PART intended for connection to AC SUPPLY MAINS. The connection to the SUPPLY MAINS of a HEARING ~~INSTRUMENT~~ AID SYSTEM is covered by power supply, charger or other types of ACCESSORIES.

~~ACCESSORIES connected to a HEARING INSTRUMENT may form a HEARING INSTRUMENT SYSTEM. Only the HEARING INSTRUMENT and its detachable parts are subject to all applicable clauses of this particular standard. The remaining components of the HEARING INSTRUMENT SYSTEM are subject to requirements of this particular standard that result from their connection to the HEARING INSTRUMENT SYSTEM.~~

~~Programming interfaces or ACCESSORIES in a clinical application are covered by the general standard.~~

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.

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

Wireless programming interfaces are covered by the applicable standard IEC 60065, IEC 60950-1, 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 ~~INSTRUMENTS~~ AIDS, even if supplied separately (e.g. ear hooks, domes, wax guards etc.), are not ~~regarded~~ considered as ACCESSORIES, but as component parts.

This document does not apply to:

- cochlear implants or other implanted HEARING ~~INSTRUMENTS~~ AIDS;
- bone conduction HEARING ~~INSTRUMENTS~~ AIDS;
- educational HEARING ~~INSTRUMENTS~~ AIDS (i.e. group HEARING ~~INSTRUMENTS~~ AIDS, auditory trainers etc.);
- the application of a HEARING ~~INSTRUMENT~~ AID for the measurement of hearing levels; IEC 60645-1 applies;
- ~~fix installed~~ audio-frequency induction-loop systems or their component parts, as described in IEC 60118-4 and IEC 62489-1;
- ~~assisted HEARING INSTRUMENT SYSTEMS using infra-red or radio;~~
- 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 ~~INSTRUMENTS~~ AIDS and HEARING ~~INSTRUMENT~~ AID SYSTEMS as defined in 201.3.202 and 201.3.203.

201.1.3 * Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

~~IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-10 and IEC 60601-1-11~~ do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 is replaced completely by the text of this particular 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.

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 ~~3.139~~ 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.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

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

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies except as follows:

Replacement:

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

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*
IEC 60950-1:2005/AMD1:2009
IEC 60950-1:2005/AMD2:2013

Addition:

IEC 60118-0:2015, *Electroacoustics – Hearing aids – Part 0: Measurement of ~~electroacoustical~~ the performance characteristics of hearing aids*

IEC 60118-13, *Electroacoustics – Hearing aids – Part 13: Electromagnetic compatibility (EMC)*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

~~IEC 62304, Medical device software – Software life cycle processes~~

~~IEC 62366:2007, Medical devices – Application of usability engineering to medical devices~~

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

201.3 Terms and definitions

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

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 56.

201.3.73

OPERATOR

Addition:

Note 101 to entry Usually equals to PATIENT for HEARING ~~instruments~~ AIDS in a home healthcare environment.

201.3.76

PATIENT

~~Addition~~

Replacement:

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.

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 ~~INSTRUMENT~~ 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 ~~INSTRUMENTS~~ AIDS or HEARING ~~INSTRUMENT~~ 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 HEALTH-CARE PROFESSIONAL~~
~~acoustician, audiologist and trained clinical staff~~

HEARING AID PROFESSIONAL

audiologically competent person who professionally assesses hearing, selects, fits and delivers HEARING AID systems and rehabilitation services to persons with hearing impairment

201.3.202

~~HEARING-INSTRUMENT~~

HEARING AID

ME EQUIPMENT which picks up sound and delivers processed sound to the ear canal through air-conduction

Note 1 to entry: A HEARING ~~INSTRUMENT~~ AID includes all detachable parts that are essential for the performance of its INTENDED USE.

201.3.203

HEARING SYSTEM

~~HEARING-INSTRUMENT~~ AID SYSTEM

combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is a HEARING ~~INSTRUMENT~~ AID to be inter-connected by specified FUNCTIONAL CONNECTIONS

201.3.204

SOUND PRESSURE LEVEL

SPL

L_p

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

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

where the reference value, p_0 , is 20 μPa

Note 1 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.

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.

Note 2 to entry: This definition is technically in accordance with ISO/FDIS 80000-8:2007/2019, 8-22.

Note 3 to entry: ~~The note to entry concerning the origin of the English abbreviation "SPL" concerns the French text only.~~ 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.]

201.3.205

MAXIMUM OUTPUT SOUND PRESSURE LEVEL

MAXIMUM OSPL90

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

201.3.206

FITTED MAXIMUM OUTPUT SOUND PRESSURE LEVEL

FITTED OSPL90

maximum output SPL of a HEARING AID when measured after fitting and 90 dB input SPL

Note 1 to entry: Since the HEARING AID parameters are not full-on, the FITTED OSPL90 is equal or lower than the MAXIMUM OSPL90. Usually, the FITTED OSPL90 is achieved by selection of a HEARING AID with an appropriate MAXIMUM OSPL90 and fine tuning of the maximum output.

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

201.4.3 ~~ESSENTIAL PERFORMANCE~~

~~Replacement:~~

~~HEARING INSTRUMENTS do not have an ESSENTIAL PERFORMANCE.~~

Addition:

See Annex CC.

201.4.6 ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Subclause 4.6 of the general standard does not apply.

201.4.10 Power supply

Subclause 4.10 of the general standard does not apply.

201.4.11 Power input

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:

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-~~INSTRUMENT~~ AID or HEARING-~~INSTRUMENT~~ 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-~~INSTRUMENT~~ AID transport conditions are specified by the MANUFACTURER.

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

Replacement:

- a) 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.
- b) HEARING-~~INSTRUMENTS~~ AID and HEARING-~~INSTRUMENT~~ AID SYSTEMS designed for more than one rated voltage shall be tested in conditions related to the least favourable voltage and nature of supply.
- c) HEARING-~~INSTRUMENTS~~ AID 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.
- d) If the instructions for use specify that a HEARING-~~INSTRUMENT~~ AID or a HEARING-~~INSTRUMENT~~ AID SYSTEM is intended to receive its power from a separate power supply, it shall be connected to such a power supply.

201.5.7 Humidity preconditioning treatment

Replacement:

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

HEARING-~~INSTRUMENTS~~ AID and HEARING-~~INSTRUMENT~~ 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-~~INSTRUMENTS~~ AID and HEARING-~~INSTRUMENT~~ AID SYSTEMS can be located, shall be maintained within $2 ^\circ\text{C}$ of any convenient value T in the range of $+20 ^\circ\text{C}$ to $+30 ^\circ\text{C}$. Before being placed in the humidity cabinet, HEARING-~~INSTRUMENTS~~ AID and HEARING-~~INSTRUMENT~~ AID SYSTEMS are brought to a temperature between T and $T + 4 ^\circ\text{C}$, and kept at this temperature for at least 4 h before the humidity treatment starts.

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

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

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

201.5.9.1 * APPLIED PARTS

Addition:

The HEARING-~~INSTRUMENT~~ AID is a TYPE B APPLIED PART in the HEARING-~~INSTRUMENT~~ AID SYSTEM. If any other parts have to be in contact with the PATIENT, those parts are also TYPE B APPLIED PARTS.

201.5.9.2 ACCESSIBLE PARTS

201.5.9.2.1 Test finger

Addition:

The tests as described in the general standard are additionally performed with the small finger probe shown in Figure 1 of IEC 60601-1-11:2010/2015.

~~201.5.201 SOUND PRESSURE LEVEL~~

~~Any sound pressure level specified in this document is measured in decibels (dB) as described in IEC 60118-0:2015.~~

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

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

201.6.2 Protection against electric shock

Replacement:

HEARING ~~INSTRUMENTS~~ AIDS are INTERNALLY POWERED, but may have connections to mains supplied equipment. The insulation between the SUPPLY MAINS and the HEARING ~~INSTRUMENT~~ AID shall be provided within the power supply, charger or other type of ACCESSORY.

The HEARING ~~INSTRUMENT~~ AID is classified a TYPE B APPLIED PART.

201.6.3 Protection against harmful ingress of water or particulate matter

Replacement:

See 201.11.6.5.

201.6.6 Mode of operation

Replacement:

HEARING ~~INSTRUMENTS~~ 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 ~~INSTRUMENT'S~~ 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 ~~instruments~~ 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 7.2 and 7.3 shall be CLEARLY LEGIBLE under the following conditions:

- safety signs and identification, on the HEARING ~~INSTRUMENT~~ 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 if necessary.

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

201.7.2.1 Minimum requirements for marking on ~~HEARING-INSTRUMENT~~ ME EQUIPMENT and on interchangeable parts

Replacement:

If the size of the HEARING ~~INSTRUMENT~~ AID does not allow affixation of all markings specified in 7.2, the markings shall be recorded in full in the ACCOMPANYING DOCUMENTS.

201.7.2.2 Identification

Replacement:

HEARING ~~INSTRUMENTS~~ AIDS shall be marked on the outside with:

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

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

- identification of right and left HEARING ~~INSTRUMENT~~ 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 ~~INSTRUMENTS~~ AIDS worn in the ear, the marking on the ~~instrument~~ HEARING AID may be reduced to the serial number and the identification of right and left. Where it is not possible, the whole applicable labelling information may be placed on the packaging for each unit.

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

- the year of manufacture.

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

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

201.7.2.5 ME EQUIPMENT intended to receive power from other equipment

Subclause 7.2.5 of the general standard does not apply.

201.7.2.6 Connection to the SUPPLY MAINS

Subclause 7.2.6 of the general standard does not apply.

201.7.2.7 Electrical input power from the SUPPLY MAINS

Subclause 7.2.7 of the general standard does not apply.

201.7.2.8 Output connectors

Subclause 7.2.8 of the general standard does not apply.

201.7.2.10 APPLIED PARTS

Subclause 7.2.10 of the general standard does not apply.

201.7.2.17 Protective packaging

Replacement:

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

201.7.8.1 * Colours of indicator lights

Replacement:

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

Compliance with the requirements is checked by inspection.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Replacement:

HEARING-~~INSTRUMENTS~~ AID~~S~~ shall be accompanied by documents containing at least the instructions for use and a technical description. The technical description may be included in the same document as the instructions for use. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the HEARING-~~INSTRUMENT~~ AID.

The ACCOMPANYING DOCUMENTS shall identify the HEARING-~~INSTRUMENT~~ AID by including, as applicable, the following:

- name or trade-name of the MANUFACTURER contact information to which the PATIENT can refer;
- MODEL OR TYPE REFERENCE;
- for HEARING-~~INSTRUMENTS~~ AID~~S~~ able to provide more than 132 dB SPL: warning to the professional OPERATOR fitting the HEARING-~~INSTRUMENT~~ AID that there may be a RISK of impairing the remaining hearing of the PATIENT.

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. electronic file format-~~on CD-ROM~~ that can be publicly downloaded.

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

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

Compliance shall be checked by inspection of the ACCOMPANYING DOCUMENTS, and, when provided electronically, as specified in IEC 60601-1-6.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Replacement:

The instructions for use shall document:

- the name or trademark and address of the MANUFACTURER;
- the MODEL OR TYPE REFERENCE;
- the purpose and INTENDED USE of the HEARING-~~INSTRUMENT~~ AID;
- the operating functions;
- identification of any known side effects associated with the use of HEARING-~~instrument~~ AID that may warrant consultation with a physician, for example accumulation of cerumen.

The instructions for use shall be in a language that is acceptable to the intended PATIENT.

The instructions for use shall include

- easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate HEARING-~~INSTRUMENT~~ AID including all controls, visual information signals, and indicators;
- easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the HEARING-~~INSTRUMENT~~ AID, ACCESSORIES and other equipment;
- any restrictions on locations or environments in which the HEARING-~~INSTRUMENT~~ AID can be used;
- advice to the PATIENT to contact the MANUFACTURER or the MANUFACTURER'S representative:
 - for assistance, if needed, in setting up, using or maintaining the HEARING-~~INSTRUMENT~~ AID or HEARING-~~INSTRUMENTS~~ AID SYSTEM; or
 - to report unexpected operation or events.

The instructions for use shall include a description and illustration on how to replace and/or recharge batteries.

201.7.9.2.2 Warning and safety notices

Replacement:

The instructions for use shall include all warning and safety notices.

General warnings and safety notices should be placed in a specifically identified section of the instructions for use. A warning or safety notice that applies only to a specific instruction or action should precede the instruction to which it applies.

Where relevant, the instructions for use shall state:

- for HEARING-~~INSTRUMENTS~~ AIDS in paediatric applications: warning to keep small parts (HEARING-~~INSTRUMENTS~~ AIDS, batteries and detachable parts) that can be swallowed out of children's reach;
- for HEARING-~~INSTRUMENTS~~ AIDS that do not comply with requirements for explosive or oxygen-enriched atmospheres: warning not to use the HEARING-~~INSTRUMENT~~ AIDS in such areas;
- warning that the specific HEARING-~~INSTRUMENT~~ must AID shall only be used by the intended person and not by others;
- for HEARING-~~INSTRUMENTS~~ AIDS with wireless transmission: warning to check first before using the HEARING AID SYSTEM in areas where electronics or wireless devices are restricted;
- statement required about the special needs of particular PATIENT groups, for example small children or mentally disabled persons;
- warning about common conditions that could damage the HEARING-~~INSTRUMENT~~ AID such as dropping, immersing in liquid, strong electromagnetic fields or excessive heat;
- other warnings that may result from the RISK assessment, for example a warning if parts could remain in the ear and what to do;
- the permissible environmental conditions of transport and storage of a HEARING-~~INSTRUMENT~~ AID after it has been removed from its protective packaging and subsequently between uses;
- for each warning and safety sign, the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK.

Warning to the HEARING AID PROFESSIONAL:

- for HEARING AIDS with 132 dB SPL or higher maximum OSPL90;

- the developed SPL in the ears of children can be substantially higher than in average adults. RECD measured to correct target of fitted OSPL90 is recommended.

201.7.9.2.4 Electrical power source

Replacement:

If leakage from a battery would result in an unacceptable risk, the instructions for use shall include a warning to remove the battery to avoid this from happening.

In case of the use of non-removable batteries, the MANUFACTURER shall advise the PATIENT in the user manual according to the RISK MANAGEMENT FILE.

201.7.9.2.5 ME EQUIPMENT description

Replacement:

The instructions for use shall include:

- a brief description of the HEARING-~~INSTRUMENT~~ AID;
- how the HEARING-~~INSTRUMENT~~ AID operates.

If the HEARING-~~INSTRUMENT~~ AID can be externally connected, the instruction for use shall state a warning only to connect to equipment that conforms to relevant international safety standards.

201.7.9.2.9 Operating instructions

Replacement:

The instructions for use shall contain all information necessary to operate the HEARING-~~INSTRUMENT~~ AID in accordance with its specification. This shall include explanation of the functions of controls, battery compartment and signals as well as connection and disconnection of user detachable parts and ACCESSORIES.

The meanings of left and right indicator symbols, warning statements, abbreviations and indicator lights on the HEARING-~~INSTRUMENT~~ AID shall be explained in the instructions for use.

201.7.9.2.12 Cleaning, disinfection and sterilization

Replacement:

The instruction for use shall contain information about cleaning and maintenance of the HEARING-~~INSTRUMENT~~ AID where applicable:

- the procedure to follow for washing the ear mould;
- replacing tubing, filters and other replaceable parts;
- storing the HEARING-~~INSTRUMENT~~ AID;
- special adequate maintenance for rechargeable batteries;
- information on how and where to obtain repair services.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Replacement:

The instructions for use shall include a list of user detachable and replaceable parts as well as ACCESSORIES.

If the HEARING-~~INSTRUMENT~~ AID is rechargeable, the instructions for use shall sufficiently specify the recharger equipment to ensure compliance with the requirements of this document.

201.7.9.2.15 Environmental protection

Replacement:

The instructions for use shall provide information about

- how to dispose of batteries;
- how to dispose of the HEARING-~~INSTRUMENT~~ AID;
- how to dispose of any part that may provide a RISK associated with the disposal.

201.7.9.2.16 Reference to the technical description

Replacement:

The instructions for use shall contain the information specified in 201.7.9.3 or a reference to where the information specified in 201.7.9.3 is to be found (e.g. in a service manual).

Compliance with the requirements of 201.7.9.2 is checked by inspection of the instructions for use in a language suitable for the intended PATIENT.

201.7.9.3 Technical description

201.7.9.3.1 General

Replacement:

The technical description shall provide all data that is essential for safe operation, transport and storage.

A technical data sheet shall be available for the professional OPERATOR fitting the HEARING-~~INSTRUMENT~~ AID. The data sheet shall include:

- a brief description of the HEARING-~~INSTRUMENT'S~~ AID'S significant physical and performance characteristics;
- technical characteristics according to IEC 60118-0;
- a unique version identifier such as its date of issue;
- a warning statement that addresses the HAZARDS that can result from unauthorized modification of the HEARING-~~INSTRUMENTS~~ AID, for example a statement to the effect:
 - "WARNING: No modification of this equipment is allowed."
 - "WARNING: Do not modify this equipment without authorization of the manufacturer."
 - "WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment."

201.8 * Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.1 Fundamental rule of protection against electric shock

Replacement:

- a) HEARING-~~INSTRUMENTS~~ AID are considered safe if supplied by an internal power source.

- b) HEARING ~~INSTRUMENTS~~ AIDS with external connections to MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601-1 and the applicable particular standards are considered safe.
- c) HEARING ~~INSTRUMENTS~~ AIDS that are normally used in a HOME HEALTHCARE ENVIRONMENT are considered safe when connected to electrical equipment in compliance with the relevant standard IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards.
~~These products shall pass the PATIENT LEAKAGE CURRENT requirements described in 201.8.7.~~

The limits specified in 201.8.4.2 shall not be exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL CONDITION.

201.8.2.1 Connection to a separate power source

Replacement:

If a HEARING ~~INSTRUMENT~~ AID is specified for connection to a separate power source, other than the SUPPLY MAINS, the separate power source shall be in compliance with the relevant standard ~~IEC 60601-1~~, IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards.

If a particular separate power supply is specified, then the relevant tests shall be performed with the HEARING ~~INSTRUMENTS~~ AIDS connected to it. If a generic separate power supply is specified, then the specification in the ACCOMPANYING DOCUMENTS shall be inspected.

201.8.3 Classification of APPLIED PARTS

Replacement:

A HEARING ~~INSTRUMENT~~ AID is classified as a TYPE B APPLIED PART.

201.8.4.2 ACCESSIBLE PARTS and APPLIED PARTS

Replacement:

- a) The requirements to PATIENT AUXILIARY CURRENT of the general standard apply. Accessible contacts of internally supplied HEARING ~~INSTRUMENTS~~ AIDS rated at ~~1,6~~ 4,5 V DC or less are exempt from these requirements as long as the DC current flowing in a realistic worst case configuration between those contacts does not exceed 10 µA and the RISK assessment covers the particular design and application.
- b) HEARING ~~INSTRUMENTS~~ AIDS connected to electrical equipment in compliance with standards other than IEC 60601 shall pass the LEAKAGE CURRENT requirements described in 201.8.7.

201.8.5 Separation of parts

Replacement:

See 201.8.1.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 General requirements

Replacement:

- a) The electrical isolation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 201.8.7.3.
- b) The specified values of this LEAKAGE CURRENT apply in any combination of the following conditions:
 - at operating temperature and following the humidity preconditioning treatment, as described in 201.5.7;

- in NORMAL CONDITION;
- with HEARING-~~INSTRUMENTS~~ AID energized in stand-by condition and fully operating.

201.8.7.2 SINGLE FAULT CONDITIONS

Subclause 8.7.2 of the general standard does not apply.

201.8.7.3 Allowable values

Replacement:

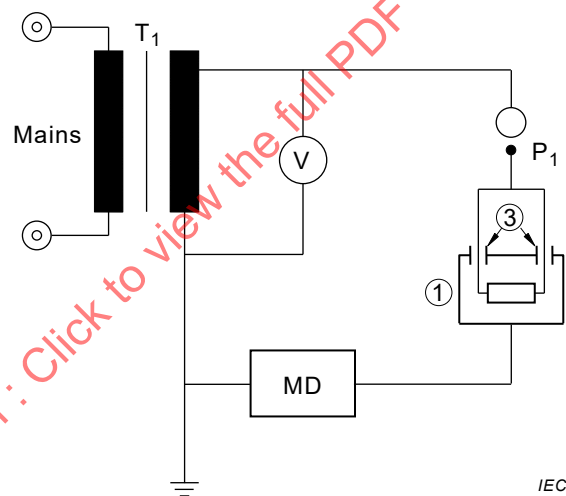
The allowable value of PATIENT LEAKAGE CURRENT is 100 μ A RMS. This value applies to current flowing through the network of Figure 12 of the general standard and measured as shown in Figure 201.101. The nominal output voltage from the isolation transformer is 275 V AC at 50 Hz or 60 Hz.

201.8.7.4 Measurements

201.8.7.4.1 General

Replacement:

The PATIENT LEAKAGE CURRENT shall be measured after the HEARING-~~instrument~~ AID has been brought up to operating temperature.



Key

- 1 HEARING-~~instrument~~ AID ENCLOSURE
- 3 SIGNAL INPUT/OUTPUT PART short circuited or loaded
- P₁ external connection
- T₁ single- or polyphase isolation transformers with sufficient power rating and adjustable output voltage (see also rationale for 8.7.4.2 of the general standard).
- V voltmeter indication RMS value, using, if relevant and possible, one meter with commutator switch
- MD measuring device (see Figure 12 of the general standard)

Figure 201.101 – Measuring circuit for LEAKAGE CURRENT (see 201.8.7.4.7)

201.8.7.4.6 Measurement of the TOUCH CURRENT

Replacement:

This subclause is covered by the requirements of 201.8.7.4.7.

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Replacement:

The HEARING-~~INSTRUMENT~~ AID is tested according to Figure 201.101 at 110 % of the highest specified mains voltage, using the appropriate measuring supply circuit.

For HEARING-~~instruments~~ AIDS that have an enclosure or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm × 10 cm is applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE.

If possible, the metal foil shall be manipulated to enable the highest value of the PATIENT LEAKAGE CURRENT to be determined.

Metal parts of the ENCLOSURE can be covered partly or totally by the metal foil.

This test need not be conducted if it can be demonstrated that there is adequate separation of the parts involved.

201.8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT

Addition:

Accessible contacts of internally supplied HEARING-~~INSTRUMENTS~~ AIDS rated at ~~1,6 V d.c. or less~~ maximum battery voltage specified by the HEARING AID MANUFACTURER are exempt from these requirements as long as the DC current flowing in a realistic worst case configuration between those contacts does not exceed 10 µA and the RISK assessment covers the particular design and application.

201.8.8 INSULATION

Replacement:

The test according to 8.7 of the general standard shall be made after the drop test of 201.15.3.4.

201.8.9 CREEPAGE DISTANCES and AIR CLEARANCES

Subclause 8.9 of the general standard does not apply.

201.8.10 Components and wiring

Subclause 8.10 of the general standard does not apply.

201.8.11 MAINS PARTS, components and layout

Subclause 8.11 of the general standard does not apply.

201.9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.1 MECHANICAL HAZARDS of ME EQUIPMENT

Replacement:

Generally, HEARING-~~INSTRUMENTS~~ AIDS with ACCESSORIES do not pose MECHANICAL HAZARDS. Table 201.~~102~~101 below lists HAZARDS that shall be considered.

Table 201.102101 – MECHANICAL HAZARDS to be considered

MECHANICAL HAZARD	Covered by subclause
Sharp edges	201.9.3
Acoustic energy	201.9.6
Entanglement	201.9.101
Parts remaining in the ear canal	201.9.102

201.9.2 MECHANICAL HAZARDS associated with moving parts

Subclause 9.2 of the general standard does not apply.

201.9.3 MECHANICAL HAZARD associated with surfaces, corners and edges

Replacement:

Rough surfaces, sharp corners and edges of HEARING ~~INSTRUMENTS~~ AIDS and HEARING ~~INSTRUMENT~~ AID SYSTEMS that could cause injury or damage shall be avoided or covered.

In particular, attention shall be paid to moulded edges, battery doors and connector flanges.

Compliance shall be checked by inspection of the HEARING ~~INSTRUMENT~~ AID or HEARING ~~INSTRUMENT~~ AID SYSTEMS.

201.9.4 Instability HAZARDS

Subclause 9.4 of the general standard does not apply.

201.9.5 Expelled parts HAZARD

Subclause 9.5 of the general standard does not apply.

201.9.6 * Acoustic energy (including infra- and ultrasound) and vibration

Replacement:

~~HEARING INSTRUMENTS with a possible maximum output SOUND PRESSURE LEVEL above 132 dB require a special warning notice (see 201.7). HEARING INSTRUMENTS shall be designed in a way that users cannot be unintentionally exposed to a SPL above 132 dB in NORMAL and SINGLE FAULT condition.~~

HEARING AIDS shall be designed in a way that users cannot be unintentionally exposed to a SPL above the FITTED OSPL90 in NORMAL CONDITION.

The acceptable level increase in SINGLE FAULT CONDITION shall be evaluated in the RISK MANAGEMENT FILE.

The FITTED OSPL90 shall be indicated on either the HEARING AID or the fitting software or otherwise. The maximum deviation shall be evaluated in the RISK MANAGEMENT FILE.

HEARING AIDS with a possible MAXIMUM OUTPUT SOUND PRESSURE LEVEL of 132 dB SPL and above require a special warning notice for the HEARING AID PROFESSIONAL (see 201.7.).

201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure

Subclause 9.7 of the general standard does not apply, because HEARING-~~INSTRUMENTS~~ AIDS do not have such parts.

201.9.8 MECHANICAL HAZARDS associated with support systems

Subclause 9.8 of the general standard does not apply, because HEARING-~~INSTRUMENTS~~ AIDS do not have such parts.

Additional subclauses:

201.9.101 HAZARD of entanglement

Cables and lanyards of HEARING-~~INSTRUMENTS~~ AIDS or ACCESSORIES worn by the PATIENT around the neck shall not pose a RISK of injury or strangulation. The disconnection force shall be no greater than 40 N.

Compliance shall be checked by applying the pull force.

201.9.102 HAZARDS of parts of a HEARING-~~INSTRUMENT~~ AID remaining in the ear canal

A HEARING-~~INSTRUMENT~~ AID that can be worn in the ear canal shall be safely retrievable by the PATIENT. If such HEARING-~~INSTRUMENT~~ AID is difficult to retrieve, a method to detect its location and to retrieve it shall be provided in the instructions for use.

HEARING-~~INSTRUMENTS~~ AIDS shall be designed in a way that parts do not come loose during use, insertion or retrieval from the ear canal.

Any part which is exposed to a pull force during the removal of a HEARING-~~INSTRUMENT~~ AID from the ear canal shall resist a force of at least 3 N without coming loose from the instrument.

Compliance shall be checked by applying the pull force test.

201.10 * Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard does not apply, except for 10.4.

~~NOTE HEARING-~~INSTRUMENTS~~ do not emit such radiation other than visible light in some cases.~~

201.11 * Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1 Excessive temperatures in ME EQUIPMENT

201.11.1.1 Maximum temperature during NORMAL USE

Replacement:

The maximum temperature of the HEARING-~~INSTRUMENT~~ AID shall not exceed 43 °C. If the surface temperature of an APPLIED PART exceeds 41 °C, the maximum temperature shall be disclosed in the instructions for use. Where 41 °C is not exceeded, no justification is required.

If the HEARING AID can operate in ambient temperatures above 43 °C, the maximum case temperature is permitted to be equal to the ambient temperature.

201.11.1.2 Temperature of APPLIED PARTS*Replacement:*

The requirements of this subclause are included in 201.11.1.1.

201.11.1.3 Measurements*Addition:*

Due to the low energy at INTERNALLY POWERED HEARING ~~INSTRUMENTS~~ AIDS, this test can typically be waived. Where engineering judgment by the MANUFACTURER indicates that temperature limits cannot be exceeded, no measurement is required. However, the rationale for such judgment shall be documented in the RISK MANAGEMENT FILE.

For HEARING ~~INSTRUMENT~~ AID parts that are likely to be touched, the probability of occurrence of contact and of the duration of contact shall be determined and documented in the RISK MANAGEMENT FILE.

Compliance with the requirements of 201.11.1.1 shall be checked by inspection of the RISK MANAGEMENT FILE and the instructions for use. ~~Operation of the HEARING INSTRUMENT and temperature measurements where necessary.~~ A temperature measurement on the HEARING AID in operation may be necessary.

201.11.2 Fire prevention

Subclause 11.2 of the general standard does not apply.

NOTE The requirements for HEARING ~~INSTRUMENTS~~ AIDS that are intended to be used in explosive and oxygen-enriched atmospheres are not contained in this particular standard.

201.11.3 Constructional requirements for fire ENCLOSURES of ME EQUIPMENT

Subclause 11.3 of the general standard does not apply.

201.11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT**201.11.6.2 Overflow in ME EQUIPMENT**

Subclause 11.6.2 of the general standard does not apply.

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Subclause 11.6.3 of the general standard does not apply.

201.11.6.4 Leakage

Subclause 11.6.4 of the general standard does not apply.

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS*Replacement:*

Normally INTERNALLY POWERED HEARING ~~INSTRUMENTS~~ AIDS do not cause electrical RISKS and do not need to be classified against the ingress of water. If the RISK assessment requires protection against harmful ingress of water or particulate matter, the IP class of the HEARING ~~INSTRUMENT~~ AID shall be not less than the level required for safe operation as detailed in IEC 60529.

Compliance shall be checked by the tests of IEC 60529 with the HEARING-~~INSTRUMENTS~~ AIDS placed in the least favourable position of NORMAL USE and by inspection.

201.11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

Replacement:

HEARING-~~INSTRUMENTS~~ AIDS and HEARING-~~INSTRUMENTS~~ AID SYSTEMS and their parts and ACCESSORIES shall be capable of withstanding, without damage or deterioration, the cleaning or disinfection PROCESSES (such as cerumen removal), as specified in the instructions for use. The MANUFACTURER shall evaluate the effects of multiple cleanings during the EXPECTED SERVICE LIFE of the HEARING-~~INSTRUMENTS~~ AIDS and HEARING-~~INSTRUMENTS~~ AID SYSTEMS, and their parts and ACCESSORIES and assure that these PROCESSES do not result in the loss of BASIC SAFETY.

Compliance shall be demonstrated by test.

201.11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

Subclause 11.6.7 of the general standard does not apply.

201.12 * Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.2 * USABILITY of ME EQUIPMENT

Addition:

PRIMARY OPERATING FUNCTIONS of HEARING-~~INSTRUMENTS~~ AIDS and SYSTEMS are identified during USABILITY ENGINEERING. Typical PRIMARY OPERATING FUNCTIONS are:

- critical functions:
 - placing and removing the HEARING-~~INSTRUMENT~~ AID;
 - ~~placing~~ fitting a HEARING-~~INSTRUMENT~~ AID;
 - testing of essential physical HEARING-~~INSTRUMENT~~ AID parameters;
- frequently used functions:
 - changing battery;
 - cleaning;
 - switching on/off;
 - adjust volume, program and other essential parameters;

NOTE See IEC 60601-1-6 for explanation of the term "frequently used functions".

201.12.4 Protection against hazardous output

201.12.4.2 Indication relevant to safety

Subclause 12.4.2 of the general standard does not apply.

201.12.4.4 Incorrect output

Replacement:

When a control adjusts ~~the intended maximum power output~~ the FITTED OSPL90, ~~output power~~ the FITTED OSPL90 shall not increase if the control is disconnected or defective.

Software controlled ~~maximum power settings~~ FITTED OSPL90 shall not exceed the selected value as a result of corrupt data transfer between programmer and HEARING ~~INSTRUMENT~~ AID.

See requirements in 201.9.6.

Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.

201.12.4.5 Diagnostic or therapeutic radiation

Subclause 12.4.5 of the general standard does not apply.

201.13 * HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.1.2 Emissions, deformation of ENCLOSURE or exceeding maximum temperature

Replacement:

The following HAZARDOUS SITUATIONS shall not occur:

- unintentional exposure to a SPL above ~~132 dB~~ the FITTED OSPL90;
- emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;
- deformation of ENCLOSURES to such an extent that compliance with 201.15.3.1 is impaired;
- temperatures of HEARING ~~INSTRUMENTS~~ AIDS that are likely to be touched, exceeding 50 °C when measured and adjusted as described in 201.11.1.3 ~~of the general standard~~;
- exceeding the allowable values for "other components and materials" identified in Table 22 of the general standard times 1,5 minus 12,5 °C.

The SINGLE FAULT CONDITIONS in 4.7 of the general standard with regard to the emission of flames, molten metal or ignitable substances shall not be applied to parts and components where:

- the construction of the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J;

Compliance shall be checked by drawing 15 W from the supply circuit for 1 min. If, after 1 min the supply circuit cannot supply 15 W, the circuit shall be considered to limit power dissipation to less than 15 W. The related design documentation is also reviewed.

or

- secondary circuits meet all of the following conditions:
 - they are mounted on material with a flammability classification of FV1 in accordance with IEC 60695-11-10 or better;
 - they are energized at a voltage of 60 V DC or 42,2 V peak or less in NORMAL and SINGLE FAULT CONDITION;
 - they are limited to 100 VA or are limited to 6 000 J in SINGLE FAULT CONDITION;
 - they employ wire insulation of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide;

Compliance is checked by evaluation of the design documentation.

or

- the component is a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS as described in 4.9 of the general standard;

Compliance is checked by evaluation of the design documentation.

or

- ~~They~~ the components are completely contained within a fire enclosure according to 11.3 of the general standard.

After the tests of this subclause, thermal cut-outs and over-current releases shall be inspected to determine that their setting has not changed (by heating, vibration or other causes) sufficiently to affect their safety function.

201.13.2 SINGLE FAULT CONDITIONS

201.13.2.1 General

Replacement:

During the application of the SINGLE FAULT CONDITIONS listed in 201.13.2.2 to 201.13.2.13 (inclusive), the NORMAL CONDITIONS identified in a) shall also be applied in the least favourable combination.

- a) NORMAL CONDITION includes all of the following simultaneously:
 - the presence on any SIGNAL INPUT/OUTPUT PART of any voltage or current from other electrical equipment that is permitted to be connected according to the ACCOMPANYING DOCUMENTS as specified in 201.7.9;
 - open circuit of any or all earth connections that do not comply with the requirements of 8.6 of the general standard, including any functional earth connection.
- b) SINGLE FAULT CONDITION includes:
 - short circuit of any one insulation that complies with the requirements for one MEANS OF PROTECTION as specified in 8.8 of the general standard;

NOTE This includes short circuiting of either constituent part of DOUBLE INSULATION that complies with 8.8 of the general standard.
 - short circuit of any one CREEPAGE DISTANCE or AIR CLEARANCE that complies with the requirements for one MEANS OF PROTECTION as specified in 8.9 of the general standard;
 - short circuit and open circuit of any component other than a COMPONENT WITH HIGH INTEGRITY CHARACTERISTICS that is connected in parallel with insulation, with an AIR CLEARANCE or with a CREEPAGE DISTANCE, unless shorting can be shown not to be a failure mode for the component (see also 4.8 and 4.9 of the general standard);
 - open circuit of any one PROTECTIVE EARTH CONDUCTOR or internal PROTECTIVE EARTH CONNECTION that complies with the requirements of 8.6 of the general standard: this does not apply to a PROTECTIVE EARTH CONDUCTOR of PERMANENTLY INSTALLED ME EQUIPMENT, which is considered unlikely to become disconnected;
 - interruption of any one power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES, if the RISK ANALYSIS indicates that this condition might cause permitted limits to be exceeded;
 - unintended movement of a component; but only if the component is not mounted securely enough to ensure that such movement will be very unlikely to occur during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, as determined by the RISK MANAGEMENT PROCESS (see also 8.10.1 of the general standard);
 - accidental detachment of conductors.

201.13.2.2 Electrical SINGLE FAULT CONDITION

Replacement:

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 201.13.2.1

201.13.2.3 Overheating of transformers in ME EQUIPMENT

Subclause 13.2.3 of the general standard does not apply, because HEARING ~~INSTRUMENTS~~ AIDS do not have transformers.

201.13.2.4 Failure of THERMOSTATS

Subclause 13.2.4 of the general standard does not apply, because HEARING ~~INSTRUMENTS~~ AIDS do not have THERMOSTATS.

201.13.2.5 Failure of temperature limiting devices

Subclause 13.2.5 of the general standard does not apply, because HEARING ~~INSTRUMENTS~~ AIDS do not have temperature limiting devices.

~~201.13.2.6 Leakage of liquid~~

~~Subclause 13.2.6 of the general standard does not apply, because HEARING ~~INSTRUMENTS~~ do not contain liquids.~~

201.13.2.7 Impairment of cooling that could result in a HAZARDOUS SITUATION

Subclause 13.2.7 of the general standard does not apply, because HEARING ~~INSTRUMENTS~~ AIDS do neither depend on ventilation nor use cooling systems.

201.13.2.8 Locking of moving parts

Subclause 13.2.8 of the general standard does not apply, because HEARING ~~INSTRUMENTS~~ AIDS do not have such moving parts.

201.13.2.9 Interruption and short circuiting of motor capacitors

Subclause 13.2.9 of the general standard does not apply, because HEARING ~~INSTRUMENTS~~ AIDS do not have motors.

201.13.2.10 Additional test criteria for motor operated ME EQUIPMENT

Subclause 13.2.10 of the general standard does not apply, because HEARING ~~INSTRUMENTS~~ AIDS do not have motors.

201.13.2.11 * Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS

Subclause 13.2.11 of the general standard does not apply.

~~NOTE The requirements for HEARING ~~INSTRUMENTS~~ that are intended to be used in explosive and oxygen-enriched atmospheres are not contained in this particular standard.~~

201.13.2.12 Failure of parts that might result in a MECHANICAL HAZARD

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in Clause 201.9 and 201.15.3.

201.13.2.13 Overload

Subclause 13.2.13 of the general standard does not apply, because HEARING ~~INSTRUMENTS~~ AIDS do not have motors or heating elements and cannot be overloaded.

201.14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard does not apply, except as follows:

201.14.1 General

Replacement:

Embedded and fitting software shall conform to IEC 62304.

The classification of software according to IEC 62304 shall be the result of the RISK ASSESSMENT.

Compliance shall be determined by application of the requirements in Clause 201.14.2 to 14.13 (inclusive), by inspection of the RISK MANAGEMENT FILE. Compliance with the IEC 62304 software design and the RISK MANAGEMENT PROCESS shall be by inspection of external or internal audit reports or certificates.

NOTE Fitting software is usually classified and treated as a medical device.

201.14.2 Documentation

Subclause 14.2 of the general standard applies.

201.14.3 RISK MANAGEMENT plan

Subclause 14.3 of the general standard applies.

201.14.6 RISK MANAGEMENT PROCESS

201.14.6.1 Identification of known and foreseeable HAZARDS

Subclause 14.6.1 of the general standard applies.

201.14.11 PEMS validation

Subclause 14.11 of the general standard applies.

201.15 * Construction of ME EQUIPMENT

Clause 15 of the general standard does not apply, except as follows:

201.15.2 Serviceability

Replacement:

Parts of HEARING-INSTRUMENTS AIDS subject to mechanical wear, electrical and environmental degradation or ageing that could result in an unacceptable RISK if allowed to continue unchecked for too long a period shall be accessible for inspection, replacement and maintenance.

Compliance shall be checked by inspection of the parts mentioned above in this subclause and of their location.

201.15.3 Mechanical strength

201.15.3.1 General

Replacement:

HEARING-~~INSTRUMENTS~~ AIDS or their parts shall have adequate mechanical strength and shall not result in loss of BASIC SAFETY due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.

For HEARING-~~INSTRUMENT~~ AID-related ACCESSORIES, IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards apply.

Mechanical design requirements for-~~instruments~~ HEARING AIDS intended for use by infants under 36 months:

- a) Battery doors shall be constructed to:
 - require a tool to remove the battery; or
 - require a force of at least 10 N in the least favourable direction to remove the battery.
- b) Any detachable part of the HEARING-~~INSTRUMENT~~ AID (e.g. ear hook, tube, type plate, programming cover) shall not be removable:
 - without a tool; or
 - with a force lower than 10 N in the direction of least resistance.

Compliance shall be checked by inspection of the product and the application of the described forces (see also 201.15.3.4).

201.15.3.4 Drop test

Replacement:

HEARING-~~INSTRUMENTS~~ AIDS shall not result in an unacceptable RISK as a result of a free fall.

Compliance shall be checked by the following test.

The sample shall be tested, with any safe working load in place, by allowing it to fall freely, once from each of six different starting orientations from a height of ~~1,5~~ 1,0 m onto a hard wood surface.

After the test, the HEARING-~~INSTRUMENT~~ AID shall not result in an unacceptable RISK, such as increased LEAKAGE CURRENT addressed in 201.8.7 or MECHANICAL HAZARDS see 201.9.

201.15.3.7 Environmental influences

Replacement:

The selection and treatment of materials used in the construction of HEARING-~~INSTRUMENTS~~ AIDS shall take account of the INTENDED USE, the EXPECTED SERVICE LIFE and the conditions for transport and storage.

The HEARING-~~INSTRUMENTS~~ AIDS shall be so designed and constructed that during its EXPECTED SERVICE LIFE any corrosion, ageing, mechanical wear, or degradation of biological materials due to the influence of moisture, sweat, humidity, hair care products or toiletries shall not reduce its mechanical properties in a way that results in an unacceptable RISK. See also 201.15.2.

Compliance shall be checked by inspection:

- of the HEARING-~~INSTRUMENTS~~ AIDS, of the ACCOMPANYING DOCUMENTS and of the MANUFACTURER'S specifications of materials used and of the processing specifications for these materials;
- of the MANUFACTURER'S relevant tests or calculations.

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.3 Batteries

201.15.4.3.1 Housing

Replacement:

Battery compartments shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in a HAZARDOUS SITUATION.

If a HAZARDOUS SITUATION might develop by the incorrect connection or replacement of a battery, the equipment shall be fitted with a means of preventing incorrect polarity.

201.15.4.3.3 Protection against overcharging

Subclause 15.4.3.3 of the general standard applies.

Additional subclause:

201.15.4.3.101 HEARING-~~INSTRUMENT~~ AID batteries

Batteries used to supply HEARING-~~INSTRUMENTS~~ AID shall comply with the relevant international standards. The design of the electronic circuit shall avoid overheating of the wrong inserted battery above 50 °C.

201.15.4.4 Indicators

Replacement:

HEARING-~~INSTRUMENTS~~ AID do not require any indicators for the PATIENT.

For HEARING-~~INSTRUMENT~~ AID-related ACCESSORIES, IEC 60950-1, IEC 60065, IEC 62368-1 or the applicable relevant IEC standard applies.

201.16 * ME SYSTEMS

Replacement:

The voltage to earth or to ACCESSIBLE PARTS other than HEARING-~~INSTRUMENTS~~ AID shall not exceed 42,4 V peak AC or 60 V DC in NORMAL CONDITION or in SINGLE FAULT CONDITION. The DC limit of 60 V applies to DC with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies. The power shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential of 2 V or more.

The voltage and energy limits specified above also apply to:

- internal parts, other than contacts of plugs, connectors and socket-outlets, that can be touched by the test pin shown in Figure 8 of the general standard inserted through an opening in an enclosure;
- internal parts that can be touched by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening in the top of an enclosure or through any opening provided for the adjustment of pre-set controls that may be adjusted by the PATIENT in NORMAL USE by using a tool.

Compliance shall be checked by inserting the test pin or the test rod through relevant openings.

The test pin shall be inserted in every possible position with minimal force (not more than 1 N).

The test rod shall be inserted in every possible position through openings provided for the adjustment of pre-set controls that can be adjusted by the PATIENT in NORMAL USE, in case of doubt with a force of 10 N.

If the instructions for use specify that a particular tool is to be used, the test is repeated with that tool.

NOTE All other system aspects are addressed in the individual clauses of this particular standard.

201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Replacement:

The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the introduction by the HEARING-~~INSTRUMENT~~ AID of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment and systems.

~~Electromagnetic compatibility shall be tested according to IEC 60118-13. Furthermore if the HEARING-INSTRUMENT has a wireless transmitter, emissions shall be tested according to relevant international radio standards.~~

Electromagnetic compatibility shall be tested in accordance with IEC 60601-1-2. For HEARING AID additional testing for immunity to digital wireless interference shall be tested according to IEC 60118-13.

See Annex DD.

Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.

Annexes

The annexes of the general standard apply, except as follows:

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Annex E
(informative)

**Examples of the connection of the measuring device (MD) for
measurement of the PATIENT LEAKAGE CURRENT and
PATIENT AUXILIARY CURRENT**

Annex E of the general standard does not apply.

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Annex G
(normative)

**Protection against HAZARDS of ignition of flammable
anaesthetic mixtures**

Annex G of the general standard does not apply.

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Annex H (informative)

PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation

Annex H of the general standard does not apply.

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Annex I
(informative)

ME SYSTEMS aspects

Annex I of the general standard does not apply.

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Annex J
(informative)

Survey of insulation paths

Annex J of the general standard does not apply.

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Annex K
(informative)

Simplified PATIENT LEAKAGE CURRENT diagrams

Annex K of the general standard does not apply.

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Annex L
(normative)

Insulated winding wires for use without interleaved insulation

Annex L of the general standard does not apply.

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Annex AA (informative)

Particular guidance and rationale

AA.1 ~~Rationale and background~~ General guidance

This document was created in order to fill a gap in standardization for HEARING-~~INSTRUMENTS~~ AIDS.

HEARING-~~INSTRUMENTS~~ AIDS have been considered inherently safe in the past. In order to fulfil regulatory requirements, MANUFACTURERS applied regulations directly by proprietary test specification based on RISK assessment and experience from trials or field data, as well as application of normative references. Due to a close cooperation of MANUFACTURERS in industrial associations, these requirements were in part coordinated and already standardized in the past. In order to create an industry standard to address regulatory requirements, an attempt was made in the 1990s, which resulted in CENELEC draft prEN 50220 in 1998. No positive voting was achieved and the European hearing instrument manufacturers association (EHIMA) released an industrial standard under its own name instead, with nearly identical content; however, this document has lacked broad acceptance. Consequently, EHIMA decided in 2009 to end this uncertainty and approached IEC with the request to produce an internationally accepted HEARING-~~INSTRUMENT~~ AIDS safety standard.

It is generally recognised by the HEARING-~~INSTRUMENT~~ AID industry and by regulators that IEC 60601-1 is not suitable to be applied to HEARING-~~INSTRUMENTS~~ AIDS. For this reason, the HEARING-~~INSTRUMENT~~ AID industry has not been participating in the activities of IEC/TC 62 and its subcommittees previously. As a result, the specification of safety requirements for HEARING-~~INSTRUMENTS~~ have AIDS has developed in a fundamentally different way compared to IEC 60601-1. Therefore, the initial approach was to create a new IEC standard outside the IEC 60601 series. The task was assigned to TC 29 "Electroacoustics" and in particular its WG 13 "Hearing Aids" in which the stakeholders in the field of audiological technology are represented. TC 62 was approached with the request for assistance and suggested the integration of this document into the IEC 60601 series in order to be in line with the structures in IEC standardization. The fundamental difference in the approach safety specifications could be accommodated by the creation of a particular standard that provides for consideration of the individual requirements due to the particular application of the products in the scope. The integration of established HEARING-~~INSTRUMENT~~ AID safety requirements into the IEC 60601 series resulted in a relatively high number of replacements of parts of the general and collateral standards.

AA.2 Definition of safety requirements for HEARING-~~INSTRUMENTS~~ AIDS

Due to the application and INTENDED USE of HEARING-~~INSTRUMENTS~~ AIDS, the risks are in many cases not comparable with those of medical products typically covered by the scope of IEC 60601-1. This document represents current best practices in the HEARING-~~INSTRUMENT~~ AID industry. This document is based on MANUFACTURER'S RISK assessments, internal standards, field trials and the evaluation of reported and known incidents and long-term experience.

The OPERATOR and the PATIENT are one and the same due to the INTENDED USE of a HEARING-~~INSTRUMENT~~ AID in a HOME HEALTHCARE ENVIRONMENT.

Table AA.101 summarizes in short the approach of this document.

Table AA.101 – Summary of the approach of this document

Subject	Risk and requirements
Electrical	There is no electrical HAZARD due to an internal supply with low voltage and low energy (typically below ~~1,6 V~~ maximum battery voltage specified by the HEARING AID MANUFACTURER and clearly within the limits of 201.8.4.2). A limit for accessible contacts at battery voltage was newly introduced in this document. Connection to external devices: Historically there are (representing the state of the art) connections to a) consumer products (audio input) or b) medical products (for programming) The RISK presented by using a HEARING ~~INSTRUMENT~~ AID is comparable with that of using an audio headphone. Requirements of IEC 60065 or IEC 60950-1 or IEC 62368-1 (or other where relevant) cover this RISK sufficiently. The RISK is extremely low, and no known incidents with HEARING ~~INSTRUMENTS~~ AID or headphones have been reported. Warning: Connect only to compliant products. An additional LEAKAGE CURRENT test to provide a minimum insulation between audio input and user was newly introduced in this document. Acceptable without further requirements.
Mechanical	Sharp edges to be avoided (also after drop test). Requirements to avoid parts from remaining in the ear. Mechanical requirements and instructions to avoid small children from swallowing parts where applicable.
Radiation	None.
Biological, Chemical	Biocompatibility testing for materials in contact with the PATIENT. Warning regarding the expansion or leakage of batteries if charged incorrectly. Marking and constructional requirements to battery door.
Heat, fire	There is no unacceptable RISK due to an internal supply with low voltage and low energy. Fault tests in this document validate this aspect. Warning regarding the expansion or leakage of batteries if charged incorrectly. Marking and constructional requirements to battery door.
Acoustical	Fault tolerant design of hardware and software (PEMS requirements) as well as programming and wireless interfaces to avoid unintentional exposure to higher levels. EMC testing required. Indication of the FITTED OSPL90 on either the HEARING AID or the fitting software. Warning to the user and ~~health care~~ HEARING AID PROFESSIONAL for ~~instruments~~ HEARING AID intentionally emitting more than 132 dB SPL.
Essential Performance	~~The failure to operate does not pose a RISK.~~
Interference	EMC and radio testing. Warnings to user about special risks, like pace makers, aircraft or explosive environment.
USABILITY	Marking in blue/red on the ~~instrument~~ HEARING AID to indicate left/right. USABILITY ENGINEERING and identification of PRIMARY OPERATING FUNCTIONS
ACCESSORY	1) Remote control and battery charger have risks comparable to IT or consumer goods (mobile phone, TV remote, etc.) and can therefore be covered sufficiently by the requirements of IEC 60065, IEC 60950-1 or IEC 62368-1 (or other where relevant). 2) Programming interfaces shall comply with IEC 60601-1. Alternative wireless programming interfaces may be covered by IEC 62368-1 or other applicable IEC safety standards.

AA.3 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document. The numbering is, therefore, not consecutive.

Clause 201.1.1 – Scope

In general, ACCESSORIES to HEARING ~~INSTRUMENTS~~ AIDS like remote control units, audio streamers, battery chargers, power supplies and similar items are used in the same environment, by the same users as entertainment, IT or household products such as mobile phones, TV remote controls etc. For that reason, the risks of these product groups are comparable and requirements of IEC 60601 general and collateral standards are often unsuitable. The application of IEC 60950-1, IEC 60065, or ~~in future~~ IEC 62368-1 will, in conjunction with this document, cover the risks appropriately. ACCESSORY is in many cases designed and/or manufactured by manufacturers in the IT or audio/video sector who are more accustomed to these requirements. This is in line with the approach of IEC 60601-1-11.

In contrast, programming interfaces or ACCESSORIES in clinical applications are operated by HEARING ~~HEALTH CARE~~ AID PROFESSIONALS in a clinical environment and should therefore be covered by the general standard.

Clause 201.1.3 – Collateral standards

~~Regarding IEC 60601-1-2 see the rationale to Clause 201.17 in this annex.~~

IEC 60601-1-9 has not been applied by the HEARING ~~INSTRUMENT~~ AID industry in the past. Compared to the ME EQUIPMENT traditionally in the scope of IEC 60601-1, HEARING ~~INSTRUMENTS~~ AIDS have a very limited environmental impact. Since this subject is covered by local legislation sufficiently and the environmental impact is not directly related to the scope of BASIC SAFETY, it was decided to not apply this collateral standard and handle the subject outside of this document.

After a review of the IEC 60601-1-11 requirements, it became apparent that HEARING ~~INSTRUMENTS~~ AIDS were not considered in the creation of this guideline resulting in a significant number of unsuitable requirements. It was deemed more feasible to consider the applicable aspects in the requirements of this particular standard rather than adopting IEC 60601-1-11 in general.

~~Subclause 201.4.3 – ESSENTIAL PERFORMANCE~~

~~hearing instruments do not have an essential performance. The failure of any function does not present a risk and is a normal occurrence once the battery is depleted. All other risks of hearing instruments are classifiable as basic safety. If a manufacturer extends the intended use to safety critical functional claims, the resulting essential performance is not covered by application of this particular standard.~~

Subclause 201.5.9.1 – APPLIED PARTS

The term "APPLIED PART" was previously not in use in the HEARING ~~INSTRUMENT~~ AID community. The symbols for APPLIED PARTS are unknown to HEARING ~~INSTRUMENT~~ AID users and OPERATORS. A marking is not needed, since HEARING ~~INSTRUMENTS~~ AIDS are always necessarily in touch with the PATIENT.

Subclause 201.7.8.1 – Colours of indicator lights

Low power consumption is essential in HEARING-INSTRUMENT AID technology. The PATIENT should not be burdened with unacceptably frequent battery change cycles or unreasonable product dimensions due to large batteries. At the state of technology now and in foreseeable future, the use of any other colours than red for an indicator light (LED) is resulting in an unacceptable consumption of energy in a HEARING-INSTRUMENT AID (background: voltage and current consumption are in direct correlation to the nature of the semi conductor material in use and as a result in direct correlation to the emitted wavelength/colour). For that reason, indicator lights are generally not required in this document and, if provided, the colour is not mandated. Indicator lights are in use, for example, in applications where PATIENTS may not express the loss of function due to young age or mental limitations. The colour red is indicating a critical situation only to personnel in clinical environment. The typical HEARING-INSTRUMENT AID user is exposed to red lights in home, office and other environments, which reduces the need of harmonization with the colour requirements of the general standard.

Clause 201.8 – Protection against electrical HAZARDS from ME EQUIPMENT

There are no electrical hazards due to an internal supply with low voltage and low energy (typically 1,4 V to 4,5 V and energy clearly within the limits of 201.16).

Connection to external devices: Historically, there are (representing the state of the art) connections to a) consumer products (audio input) or b) medical products (for programming). The RISK of a HEARING-INSTRUMENT AID is comparable to an audio headphone. Electrical insulation requirements of IEC 60065, IEC 60950-1 or IEC 62368-1 (or other applicable standards where relevant) cover this RISK sufficiently. No incidents with HEARING-INSTRUMENTS AIDS or audio headphones have been reported. 201.7.9.2.5 requires an instruction to connect HEARING-INSTRUMENTS AIDS only to standard compliant products.

For these reasons, generally no insulation is required in a HEARING-INSTRUMENT AID. Except in case of external connections to non-medical products, where an additional LEAKAGE CURRENT test between signal input and user is required in 201.8.7.

Accessible contacts at less than ~~1,6~~ 4.5 V direct current of internally supplied HEARING-INSTRUMENTS AIDS were not regulated before publication of this document and did not result in harm or injury. Measurement results in worst case situation between contacts resulted in actual DC currents clearly below 10 µA. A limit for PATIENT auxiliary circuits was introduced in 201.8.4.2 ~~of this document~~.

Clause 201.9 – Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

MECHANICAL HAZARDS of HEARING-INSTRUMENTS AIDS are limited to the following items that are covered in this clause:

- sharp edges to be avoided (also after drop test);
- requirements to avoid parts from remaining in the ear (the 3 N requirement in 201.9.102 is derived from the extraction force of ~~an instrument~~ a HEARING AID);
- mechanical requirements and instructions to avoid small children from swallowing parts where applicable.

Subclause 201.9.6 – Acoustic energy (including infra- and ultrasound) and vibration

~~The rationale for choosing 132 dB as a critical level derives from Directive 2003/10/EC, and 29 CFR 1910.95 OSHA, which state that a noise above 140 dB is not allowed regardless of duration. Considering the intent to deliver elevated sound to a patient for compensation of a hearing impairment, it was decided to follow earlier EHIMA recommendations (e.g. Draft prEN 50220), homologation practice (e.g. NSH), FDA guidance (21 CFR 801.420 Hearing aid~~

~~devices) and established practice in the community by requiring particular measures above a 132 dB level (see also labelling requirements in 201.7.9.2.2).~~

The maximum acceptable SOUND PRESSURE LEVEL, which does not cause discomfort or further hearing damage, depends on the individual uncomfortable loudness level (UCL).

During the fitting PROCESS, the maximum output level of the HEARING AID, in this document referred to as fitted maximum SOUND PRESSURE LEVEL (FITTED OSPL90), is adjusted as required by the individual (e.g. by HEARING AID PROFESSIONAL).

The FITTED OSPL90 is understood as the actual maximum output level at the end of the fitting.

In SINGLE FAULT CONDITION, the actual maximum output level may increase somewhat depending on the technical implementation, for example to keep sound distortion low in NORMAL CONDITION.

The indicated FITTED OSPL90 (e.g. in the fitting software) is derived by computation based on the settings of the HEARING AID and therefore may deviate from the actual level.

HEARING AIDS with output level 132 dB and above (measured according to IEC 60118-0, using a coupler according to IEC 60318-5) require labelling to make the HEARING AID PROFESSIONAL aware that SOUND PRESSURE LEVELS in this range also for a short period of time may cause hearing damage to those with normal hearing. The SPL on 132 dB in the coupler is equivalent to about 135 dB in free-field conditions at 1 kHz. The requirement for a warning for HEARING AIDS with a MAXIMUM OSPL90 of 132 dB or higher is derived from the FDA guidance 21 CFR 801.420. The value of 135 dB is also in agreement with the lower exposurer action peak value of Article 3 of the Directive 2003/10/EC.

Clause 201.10 – Protection against unwanted and excessive radiation hazards

HEARING AIDS do not emit such radiation other than visible light in some cases.

Clause 201.11 – Protection against excessive temperatures and other HAZARDS

Usually, there is no unacceptable RISK of fire, heat or ignition due to an internal supply with low voltage and low energy. Most requirements of the general standard are therefore not applicable and temperature measurements are typically not required.

Subclause 201.12.2 – USABILITY of ME EQUIPMENT

Compared to the ME EQUIPMENT traditionally in the scope of IEC 60601-1, HEARING ~~INSTRUMENTS~~ AIDS have very limited USABILITY aspects. Typical examples for PRIMARY OPERATING FUNCTIONS are listed here and might not apply. USABILITY ENGINEERING may also lead to further PRIMARY OPERATING FUNCTIONS.

Clause 201.13 – HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Due to the absence of electrical hazards, fire and heat hazards (see Annex AA clause 201.8 and 201.11), many requirements of this clause of the general standard are not applicable.

Subclause 201.13.2.11 – Failures of components in me equipment used in conjunction with oxygen rich environments

The requirements for HEARING AID that are intended to be used in explosive and oxygen enriched atmospheres are not contained in this particular standard.

Clause 201.14 – PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

In line with the low risks caused by HEARING ~~INSTRUMENTS~~ AIDS compared to ME EQUIPMENT traditionally in the scope of IEC 60601-1, the software for HEARING ~~INSTRUMENTS~~ AIDS is rather uncritical and of lower complexity. Historically, the HEARING ~~INSTRUMENT~~ AID industry has applied IEC 62304 and not IEC 60601-1-4². Since this approach is now established and has proven appropriate, it is not deemed necessary to follow the approach of the third edition of IEC 60601-1 to tailor and specify the IEC 62304 requirements.

Clause 201.15 – Construction of ME EQUIPMENT

Due to the absence of electrical hazards, fire and heat hazards (see Annex AA, Clauses 201.8 and 201.11), many requirements of this clause of the general standard are not applicable.

Clause 201.16 – ME SYSTEMS

This clause of the general standard was deemed too extensive to be applied to the few minor system aspects of HEARING ~~INSTRUMENT~~ AID SYSTEMS. All system aspects were addressed in the individual clauses of this particular standard instead, supporting an easier application of this document.

~~Clause 201.17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS~~

~~IEC TC 29 has produced IEC 60118-13 as an EMC standard for HEARING INSTRUMENTS. That standard is established and more suitable to the products in the scope of this document than IEC 60601-1-2.~~

² The IEC 60601-1-4:1996 and its Amendment 1:1999 have been withdrawn. No new edition of that publication has been planned at the time of publication of this document.

Annex BB (informative)

Abbreviations

CD	Committee Draft (IEC document status)
EHIMA	European hearing instrument manufacturers association
FDA	Food and Drug Administration
LED	light emitting diode
ME	medical electrical
NSH	Nordic cooperation on disability
NWIP	New Work Item Proposal (IEC document status)
OSHA	~~Organizational~~ Occupational Safety and Health Administration (USA)
PEMS	programmable electrical medical system
RECD	real ear to coupler difference

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Annex CC
(informative)

Essential performance

After a careful consideration of the clauses within this document, it was decided that they all deal with BASIC SAFETY as defined in the general standard. MANUFACTURERS have the ability to identify functions of HEARING AIDS which are considered ESSENTIAL PERFORMANCE in accordance with their RISK MANAGEMENT PROCESS.

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Annex DD (informative)

Electromagnetic compatibility of ME EQUIPMENT

Electromagnetic compatibility shall be tested according to IEC 60601-1-2. Any RISK shall be evaluated by the RISK MANAGEMENT.

Additionally, for HEARING AIDS immunity to radiated EM fields, requirements as specified in IEC 60118-13 (for USA ANSI C63.19) apply.

Table DD.101 shows an example of applicable standards for HEARING AID specific setting for RF radiated emissions.

**Table DD.101 – Example of applicable standards for HEARING AID
specific setting for RF radiated emissions**

Phenomenon	Applicable standard for HOME HEALTHCARE ENVIRONMENT	Setting of HEARING AID during the test
Radiated RF emissions of HEARING AID	CISPR 11, Group 1, Class B	Reference test setting as per IEC 60118-0

The MANUFACTURER should determine the appropriate test settings and requirements for their product. Table DD.102 is an example that can be used to help determine HEARING AIDS specific test settings and requirements for BASIC SAFETY and minimum immunity performance requirements.

This example is not a recommendation or suggested guideline. Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.

Table DD.102 – Example of applicable tests

Phenomenon	Immunity test levels for HOME HEALTHCARE ENVIRONMENT	Setting of the HEARING AID during the test	Pass/fail criteria for BASIC SAFETY	Minimum performance requirement for HEARING AIDS without radio function
ELECTROSTATIC DISCHARGE	a Level 4: ±8kV contact; ±2 kV; ±4 kV; ±8kV; ±15 kV air	b Full-on gain, with OSPL90 reduced by at least 10 dB	c For all levels: The output level with 90 dB input level shall not increase by more than 6 dB after ESD exposure, degradation acceptable.	HEARING AID shall withstand without degradation: a) level 2 without user interaction ±4 kV contact; ±4 kV air b) level 3 with user interaction (e.g. restart HEARING AID) ±6 kV contact; ±2 kV; ± 4 kV; ±8 kV air
Power frequency magnetic fields (PFMF)	30 A/m 50 Hz or 60 Hz (test according to IEC 61000-4-8)	Reference test setting as per IEC 60118-0	e N/a	d IRIL _{PFMF} = overall output interference level minus HFA ≤ 55 dB

a Levels see IEC 61000-4-2.

b In order to be able to detect a possible increase of output level, the OSPL90 shall be set to at least 10 dB lower than the OSPL90 prior to testing.

c The output level with 90 dB input is measured before and after ESD exposure.

d Approach is to be determined.

e N/a, because no safety relevant failure expected (similar like exposure to radiated RF fields).

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ISO/TR 25417:2007, *Acoustics – Definitions of basic quantities and terms*

ISO/FDIS 80000-8:~~2007~~2019, *Quantities and units – Part 8: Acoustics*⁴

Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise)

European Medical Device Directive 93/42/EEC

³ The IEC 60601-1-4:1996 and its Amendment 1:1999 have been withdrawn. No new edition of that publication has been planned at the time of publication of this document.

⁴ Under preparation. Stage at the time of publication: ISO/FDIS 80008-8:2019

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-66: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de correction auditive et des systèmes de correction auditive

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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

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60601-2-66 has been prepared by IEC technical committee 29: Electroacoustics.

This third edition cancels and replaces the second edition published in 2015. It constitutes a technical revision.

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

- a) revision of the definition about ESSENTIAL PERFORMANCE;
- b) revision of the application of IEC 60601-1-2:2014 for electromagnetic disturbances;
- c) correction of the used voltage for HEARING AIDS from 1,6 V to 4,5 V;
- d) correction of the drop test level from 1,5 m to 1,0 m;
- e) correction of the wording of IEC 60601-2-66:2015.

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

FDIS	Report on voting
29/1023/FDIS	29/1030/RVD

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

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

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 conjunctive "or" is used as an "inclusive or" so a statement is true if any combination 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 Annex AA.

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 "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION

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

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

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

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

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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 except in 201.7.9.2 and 201.9.6.

NOTE See also 4.2 of the general standard.

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 60065, IEC 60950-1, 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 60065, IEC 60950-1, 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, *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;
- fix installed 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

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 is replaced completely by the text of this particular 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.

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.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

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

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies except as follows:

Replacement:

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

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*

IEC 60950-1:2005/AMD1:2009

IEC 60950-1:2005/AMD2:2013

Addition:

IEC 60118-0:2015, *Electroacoustics – Hearing aids – Part 0: Measurement of the performance characteristics of hearing aids*

IEC 60118-13, *Electroacoustics – Hearing aids – Part 13: Electromagnetic compatibility (EMC)*

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

IEC 60601-1:2005/AMD1:2012

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 and IEC 60601-1:2005/AMD1:2012 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 54.

201.3.73

OPERATOR

Addition:

Note 101 to entry Usually equals to PATIENT for HEARING AIDS in a home healthcare environment.

201.3.76

PATIENT

Replacement:

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.

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 PROFESSIONAL

audiologically competent person who professionally assesses hearing, selects, fits and delivers HEARING AID systems and rehabilitation services to persons with hearing impairment

201.3.202

HEARING AID

ME EQUIPMENT which picks up sound and delivers processed sound to the ear canal through air-conduction

Note 1 to entry: A HEARING AID includes all detachable parts that are essential for the performance of its INTENDED USE.

201.3.203

HEARING SYSTEM

HEARING AID 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

201.3.204

SOUND PRESSURE LEVEL

SPL

L_p

ten times the logarithm to the base 10 of the ratio 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

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

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.

Note 2 to entry: This definition is technically in accordance with ISO/FDIS 80000-8:2019, 8-22.

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.]

201.3.205

MAXIMUM OUTPUT SOUND PRESSURE LEVEL

MAXIMUM OSPL90

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

201.3.206

FITTED MAXIMUM OUTPUT SOUND PRESSURE LEVEL

FITTED OSPL90

maximum output SPL of a HEARING AID when measured after fitting and 90 dB input SPL

Note 1 to entry: Since the HEARING AID parameters are not full-on, the FITTED OSPL90 is equal or lower than the MAXIMUM OSPL90. Usually, the FITTED OSPL90 is achieved by selection of a HEARING AID with an appropriate MAXIMUM OSPL90 and fine tuning of the maximum output.

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.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

See Annex CC.

201.4.6 ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Subclause 4.6 of the general standard does not apply.

201.4.10 Power supply

Subclause 4.10 of the general standard does not apply.

201.4.11 Power input

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:

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:

- a) 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.
- b) 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.
- c) 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.
- d) If the instructions for use specify that a HEARING AID or a HEARING AID SYSTEM is intended to receive its power from a separate power supply, it shall be connected to such a power supply.

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 $2\text{ }^{\circ}\text{C}$ of any convenient value T in the range of $+20\text{ }^{\circ}\text{C}$ to $+30\text{ }^{\circ}\text{C}$. Before being placed in the humidity cabinet, HEARING AIDS and HEARING AID SYSTEMS are brought to a temperature between T and $T + 4\text{ }^{\circ}\text{C}$, 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.

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

201.5.9.1 * APPLIED PARTS

Addition:

The HEARING AID is a TYPE B APPLIED PART in the HEARING AID SYSTEM. If any other parts have to be in contact with the PATIENT, those parts are also TYPE B APPLIED PARTS.

201.5.9.2 ACCESSIBLE PARTS

201.5.9.2.1 Test finger

Addition:

The tests as described in the general standard are additionally performed with the small finger probe shown in Figure 1 of IEC 60601-1-11:2015.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

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

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.

The HEARING AID is classified a TYPE B APPLIED PART.

201.6.3 Protection against harmful ingress of water or particulate matter

Replacement:

See 201.11.6.5.

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 7.2 and 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 if necessary.

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:

If the size of the HEARING AID does not allow affixation of all markings specified in 7.2, the markings shall be recorded in full in the ACCOMPANYING DOCUMENTS.

201.7.2.2 Identification

Replacement:

HEARING AIDS shall be marked on the outside with:

- the name 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, the marking on the HEARING AID may be reduced to the serial number and the identification of right and left. Where it is not possible, the whole applicable labelling information may be placed on the packaging for each unit.

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

- the year of manufacture.

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

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

201.7.2.5 ME EQUIPMENT intended to receive power from other equipment

Subclause 7.2.5 of the general standard does not apply.

201.7.2.6 Connection to the SUPPLY MAINS

Subclause 7.2.6 of the general standard does not apply.

201.7.2.7 Electrical input power from the SUPPLY MAINS

Subclause 7.2.7 of the general standard does not apply.

201.7.2.8 Output connectors

Subclause 7.2.8 of the general standard does not apply.

201.7.2.10 APPLIED PARTS

Subclause 7.2.10 of the general standard does not apply.

201.7.2.17 Protective packaging

Replacement:

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

201.7.8.1 * Colours of indicator lights

Replacement:

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

Compliance with the requirements is checked by inspection.

201.7.9 ACCOMPANYING DOCUMENTS**201.7.9.1 General**

Replacement:

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

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

- name or trade-name of the MANUFACTURER contact information to which the PATIENT can refer;
- MODEL OR TYPE REFERENCE;
- for HEARING AIDS able to provide more than 132 dB SPL: warning to the professional OPERATOR fitting the HEARING AID that there may be a RISK of impairing the remaining hearing of the PATIENT.

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. electronic file format that can be publicly downloaded.

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

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

Compliance shall be checked by inspection of the ACCOMPANYING DOCUMENTS, and, when provided electronically, as specified in IEC 60601-1-6.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Replacement:

The instructions for use shall document:

- the name or trademark and address of the MANUFACTURER;
- the MODEL OR TYPE REFERENCE;
- the purpose and INTENDED USE of the HEARING AID;
- the operating functions;
- identification of any known side effects associated with the use of HEARING AID that may warrant consultation with a physician, for example accumulation of cerumen.

The instructions for use shall be in a language that is acceptable to the intended PATIENT.

The instructions for use shall include

- easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate HEARING AID including all controls, visual information signals, and indicators;
- easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the HEARING AID, ACCESSORIES and other equipment;
- any restrictions on locations or environments in which the HEARING AID can be used;
- advice to the PATIENT to contact the MANUFACTURER or the MANUFACTURER'S representative:
 - for assistance, if needed, in setting up, using or maintaining the HEARING AID or HEARING AID SYSTEM; or
 - to report unexpected operation or events.

The instructions for use shall include a description and illustration on how to replace and/or recharge batteries.

201.7.9.2.2 Warning and safety notices

Replacement:

The instructions for use shall include all warning and safety notices.

General warnings and safety notices should be placed in a specifically identified section of the instructions for use. A warning or safety notice that applies only to a specific instruction or action should precede the instruction to which it applies.

Where relevant, the instructions for use shall state:

- for HEARING AIDS in paediatric applications: warning to keep small parts (HEARING AIDS, batteries and detachable parts) that can be swallowed out of children's reach;
- for HEARING AIDS that do not comply with requirements for explosive or oxygen-enriched atmospheres: warning not to use the HEARING AIDS in such areas;
- warning that the specific HEARING AID shall only be used by the intended person and not by others;
- for HEARING AIDS with wireless transmission: warning to check first before using the HEARING AID SYSTEM in areas where electronics or wireless devices are restricted;
- statement required about the special needs of particular PATIENT groups, for example small children or mentally disabled persons;

- warning about common conditions that could damage the HEARING AID such as dropping, immersing in liquid, strong electromagnetic fields or excessive heat;
- other warnings that may result from the RISK assessment, for example a warning if parts could remain in the ear and what to do;
- the permissible environmental conditions of transport and storage of a HEARING AID after it has been removed from its protective packaging and subsequently between uses;
- for each warning and safety sign, the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK.

Warning to the HEARING AID PROFESSIONAL:

- for HEARING AIDS with 132 dB SPL or higher maximum OSPL90;
- the developed SPL in the ears of children can be substantially higher than in average adults. RECD measured to correct target of fitted OSPL90 is recommended.

201.7.9.2.4 Electrical power source

Replacement:

If leakage from a battery would result in an unacceptable risk, the instructions for use shall include a warning to remove the battery to avoid this from happening.

In case of the use of non-removable batteries, the MANUFACTURER shall advise the PATIENT in the user manual according to the RISK MANAGEMENT FILE.

201.7.9.2.5 ME EQUIPMENT description

Replacement:

The instructions for use shall include:

- a brief description of the HEARING AID;
- how the HEARING AID operates.

If the HEARING AID can be externally connected, the instruction for use shall state a warning only to connect to equipment that conforms to relevant international safety standards.

201.7.9.2.9 Operating instructions

Replacement:

The instructions for use shall contain all information necessary to operate the HEARING AID in accordance with its specification. This shall include explanation of the functions of controls, battery compartment and signals as well as connection and disconnection of user detachable parts and ACCESSORIES.

The meanings of left and right indicator symbols, warning statements, abbreviations and indicator lights on the HEARING AID shall be explained in the instructions for use.

201.7.9.2.12 Cleaning, disinfection and sterilization

Replacement:

The instruction for use shall contain information about cleaning and maintenance of the HEARING AID where applicable:

- the procedure to follow for washing the ear mould;
- replacing tubing, filters and other replaceable parts;

- storing the HEARING AID;
- special adequate maintenance for rechargeable batteries;
- information on how and where to obtain repair services.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Replacement:

The instructions for use shall include a list of user detachable and replaceable parts as well as ACCESSORIES.

If the HEARING AID is rechargeable, the instructions for use shall sufficiently specify the recharger equipment to ensure compliance with the requirements of this document.

201.7.9.2.15 Environmental protection

Replacement:

The instructions for use shall provide information about

- how to dispose of batteries;
- how to dispose of the HEARING AID;
- how to dispose of any part that may provide a RISK associated with the disposal.

201.7.9.2.16 Reference to the technical description

Replacement:

The instructions for use shall contain the information specified in 201.7.9.3 or a reference to where the information specified in 201.7.9.3 is to be found (e.g. in a service manual).

Compliance with the requirements of 201.7.9.2 is checked by inspection of the instructions for use in a language suitable for the intended PATIENT.

201.7.9.3 Technical description

201.7.9.3.1 General

Replacement:

The technical description shall provide all data that is essential for safe operation, transport and storage.

A technical data sheet shall be available for the professional OPERATOR fitting the HEARING AID. The data sheet shall include:

- a brief description of the HEARING AID'S significant physical and performance characteristics;
- technical characteristics according to IEC 60118-0;
- a unique version identifier such as its date of issue;
- a warning statement that addresses the HAZARDS that can result from unauthorized modification of the HEARING AIDS, for example a statement to the effect:
 - "WARNING: No modification of this equipment is allowed."
 - "WARNING: Do not modify this equipment without authorization of the manufacturer."
 - "WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment."

201.8 * Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.1 Fundamental rule of protection against electric shock

Replacement:

- a) HEARING AIDS are considered safe if supplied by an internal power source.
- b) HEARING AIDS with external connections to MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601-1 and the applicable particular standards are considered safe.
- c) HEARING AIDS that are normally used in a HOME HEALTHCARE ENVIRONMENT are considered safe when connected to electrical equipment in compliance with the relevant standard IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards.

The limits specified in 201.8.4.2 shall not be exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL CONDITION.

201.8.2.1 Connection to a separate power source

Replacement:

If a HEARING AID is specified for connection to a separate power source, other than the SUPPLY MAINS, the separate power source shall be in compliance with the relevant standard, IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards.

If a particular separate power supply is specified, then the relevant tests shall be performed with the HEARING AIDS connected to it. If a generic separate power supply is specified, then the specification in the ACCOMPANYING DOCUMENTS shall be inspected.

201.8.3 Classification of APPLIED PARTS

Replacement:

A HEARING AID is classified as a TYPE B APPLIED PART.

201.8.4.2 ACCESSIBLE PARTS and APPLIED PARTS

Replacement:

- a) The requirements to PATIENT AUXILIARY CURRENT of the general standard apply. Accessible contacts of internally supplied HEARING AIDS rated at 4,5 V DC or less are exempt from these requirements as long as the DC current flowing in a realistic worst case configuration between those contacts does not exceed 10 μ A and the RISK assessment covers the particular design and application.
- b) HEARING AIDS connected to electrical equipment in compliance with standards other than IEC 60601 shall pass the LEAKAGE CURRENT requirements described in 201.8.7.

201.8.5 Separation of parts

Replacement:

See 201.8.1.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 General requirements

Replacement:

- a) The electrical isolation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 201.8.7.3.
- b) The specified values of this LEAKAGE CURRENT apply in any combination of the following conditions:
 - at operating temperature and following the humidity preconditioning treatment, as described in 201.5.7;
 - in NORMAL CONDITION;
 - with HEARING AIDS energized in stand-by condition and fully operating.

201.8.7.2 SINGLE FAULT CONDITIONS

Subclause 8.7.2 of the general standard does not apply.

201.8.7.3 Allowable values

Replacement:

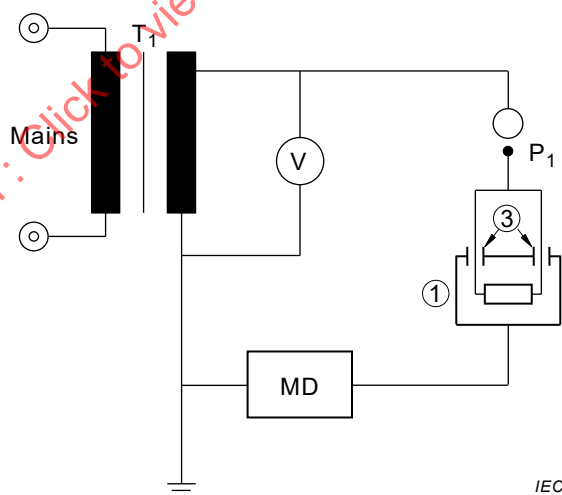
The allowable value of PATIENT LEAKAGE CURRENT is 100 μ A RMS. This value applies to current flowing through the network of Figure 12 of the general standard and measured as shown in Figure 201.101. The nominal output voltage from the isolation transformer is 275 V AC at 50 Hz or 60 Hz.

201.8.7.4 Measurements

201.8.7.4.1 General

Replacement:

The PATIENT LEAKAGE CURRENT shall be measured after the HEARING AID has been brought up to operating temperature.



Key

- 1 HEARING AID ENCLOSURE
- 3 SIGNAL INPUT/OUTPUT PART short circuited or loaded
- P_1 external connection
- T_1 single- or polyphase isolation transformers with sufficient power rating and adjustable output voltage (see also rationale for 8.7.4.2 of the general standard).
- V voltmeter indication RMS value, using, if relevant and possible, one meter with commutator switch
- MD measuring device (see Figure 12 of the general standard)

Figure 201.101 – Measuring circuit for LEAKAGE CURRENT (see 201.8.7.4.7)

201.8.7.4.6 Measurement of the TOUCH CURRENT

Replacement:

This subclause is covered by the requirements of 201.8.7.4.7.

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Replacement:

The HEARING AID is tested according to Figure 201.101 at 110 % of the highest specified mains voltage, using the appropriate measuring supply circuit.

For HEARING AIDS that have an enclosure or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm × 10 cm is applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE.

If possible, the metal foil shall be manipulated to enable the highest value of the PATIENT LEAKAGE CURRENT to be determined.

Metal parts of the ENCLOSURE can be covered partly or totally by the metal foil.

This test need not be conducted if it can be demonstrated that there is adequate separation of the parts involved.

201.8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT

Addition:

Accessible contacts of internally supplied HEARING AIDS rated at maximum battery voltage specified by the HEARING AID MANUFACTURER are exempt from these requirements as long as the DC current flowing in a realistic worst case configuration between those contacts does not exceed 10 µA and the RISK assessment covers the particular design and application.

201.8.8 INSULATION

Replacement:

The test according to 8.7 of the general standard shall be made after the drop test of 201.15.3.4.

201.8.9 CREEPAGE DISTANCES and AIR CLEARANCES

Subclause 8.9 of the general standard does not apply.

201.8.10 Components and wiring

Subclause 8.10 of the general standard does not apply.

201.8.11 MAINS PARTS, components and layout

Subclause 8.11 of the general standard does not apply.

201.9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.1 MECHANICAL HAZARDS OF ME EQUIPMENT

Replacement:

Generally, HEARING AIDS with ACCESSORIES do not pose MECHANICAL HAZARDS. Table 201.101 below lists HAZARDS that shall be considered.

Table 201.101 – MECHANICAL HAZARDS to be considered

MECHANICAL HAZARD	Covered by subclause
Sharp edges	201.9.3
Acoustic energy	201.9.6
Entanglement	201.9.101
Parts remaining in the ear canal	201.9.102

201.9.2 MECHANICAL HAZARDS associated with moving parts

Subclause 9.2 of the general standard does not apply.

201.9.3 MECHANICAL HAZARD associated with surfaces, corners and edges

Replacement:

Rough surfaces, sharp corners and edges of HEARING AIDS and HEARING AID SYSTEMS that could cause injury or damage shall be avoided or covered.

In particular, attention shall be paid to moulded edges, battery doors and connector flanges.

Compliance shall be checked by inspection of the HEARING AID or HEARING AID SYSTEMS.

201.9.4 Instability HAZARDS

Subclause 9.4 of the general standard does not apply.

201.9.5 Expelled parts HAZARD

Subclause 9.5 of the general standard does not apply.

201.9.6 * Acoustic energy (including infra- and ultrasound) and vibration

Replacement:

HEARING AIDS shall be designed in a way that users cannot be unintentionally exposed to a SPL above the FITTED OSPL90 in NORMAL CONDITION.

The acceptable level increase in SINGLE FAULT CONDITION shall be evaluated in the RISK MANAGEMENT FILE.

The FITTED OSPL90 shall be indicated on either the HEARING AID or the fitting software or otherwise. The maximum deviation shall be evaluated in the RISK MANAGEMENT FILE.

HEARING AIDS with a possible MAXIMUM OUTPUT SOUND PRESSURE LEVEL of 132 dB SPL and above require a special warning notice for the HEARING AID PROFESSIONAL (see 201.7.).

201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure

Subclause 9.7 of the general standard does not apply, because HEARING AIDS do not have such parts.

201.9.8 MECHANICAL HAZARDS associated with support systems

Subclause 9.8 of the general standard does not apply, because HEARING AIDS do not have such parts.

Additional subclauses:

201.9.101 HAZARD of entanglement

Cables and lanyards of HEARING AIDS or ACCESSORIES worn by the PATIENT around the neck shall not pose a RISK of injury or strangulation. The disconnection force shall be no greater than 40 N.

Compliance shall be checked by applying the pull force.

201.9.102 HAZARDS of parts of a HEARING AID remaining in the ear canal

A HEARING AID that can be worn in the ear canal shall be safely retrievable by the PATIENT. If such HEARING AID is difficult to retrieve, a method to detect its location and to retrieve it shall be provided in the instructions for use.

HEARING AIDS shall be designed in a way that parts do not come loose during use, insertion or retrieval from the ear canal.

Any part which is exposed to a pull force during the removal of a HEARING AID from the ear canal shall resist a force of at least 3 N without coming loose from the instrument.

Compliance shall be checked by applying the pull force test.

201.10 * Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard does not apply, except for 10.4.

201.11 * Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1 Excessive temperatures in ME EQUIPMENT**201.11.1.1 Maximum temperature during NORMAL USE**

Replacement:

The maximum temperature of the HEARING AID shall not exceed 43 °C. If the surface temperature of an APPLIED PART exceeds 41 °C, the maximum temperature shall be disclosed in the instructions for use. Where 41 °C is not exceeded, no justification is required.

If the HEARING AID can operate in ambient temperatures above 43 °C, the maximum case temperature is permitted to be equal to the ambient temperature.

201.11.1.2 Temperature of APPLIED PARTS

Replacement:

The requirements of this subclause are included in 201.11.1.1.

201.11.1.3 Measurements

Addition:

Due to the low energy at INTERNALLY POWERED HEARING AIDS, this test can typically be waived. Where engineering judgment by the MANUFACTURER indicates that temperature limits cannot be exceeded, no measurement is required. However, the rationale for such judgment shall be documented in the RISK MANAGEMENT FILE.

For HEARING AID parts that are likely to be touched, the probability of occurrence of contact and of the duration of contact shall be determined and documented in the RISK MANAGEMENT FILE.

Compliance with the requirements of 201.11.1.1 shall be checked by inspection of the RISK MANAGEMENT FILE and the instructions for use. A temperature measurement on the HEARING AID in operation may be necessary.

201.11.2 Fire prevention

Subclause 11.2 of the general standard does not apply.

NOTE The requirements for HEARING AIDS that are intended to be used in explosive and oxygen-enriched atmospheres are not contained in this particular standard.

201.11.3 Constructional requirements for fire ENCLOSURES of ME EQUIPMENT

Subclause 11.3 of the general standard does not apply.

201.11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

201.11.6.2 Overflow in ME EQUIPMENT

Subclause 11.6.2 of the general standard does not apply.

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Subclause 11.6.3 of the general standard does not apply.

201.11.6.4 Leakage

Subclause 11.6.4 of the general standard does not apply.

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Replacement:

Normally INTERNALLY POWERED HEARING AIDS do not cause electrical RISKS and do not need to be classified against the ingress of water. If the RISK assessment requires protection against harmful ingress of water or particulate matter, the IP class of the HEARING AID shall be not less than the level required for safe operation as detailed in IEC 60529.

Compliance shall be checked by the tests of IEC 60529 with the HEARING AIDS placed in the least favourable position of NORMAL USE and by inspection.

201.11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS*Replacement:*

HEARING AIDS and HEARING AID SYSTEMS and their parts and ACCESSORIES shall be capable of withstanding, without damage or deterioration, the cleaning or disinfection PROCESSES (such as cerumen removal), as specified in the instructions for use. The MANUFACTURER shall evaluate the effects of multiple cleanings during the EXPECTED SERVICE LIFE of the HEARING AIDS and HEARING AID SYSTEMS, and their parts and ACCESSORIES and assure that these PROCESSES do not result in the loss of BASIC SAFETY.

Compliance shall be demonstrated by test.

201.11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

Subclause 11.6.7 of the general standard does not apply.

201.12 * Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.2 * USABILITY of ME EQUIPMENT*Addition:*

PRIMARY OPERATING FUNCTIONS of HEARING AIDS and SYSTEMS are identified during USABILITY ENGINEERING. Typical PRIMARY OPERATING FUNCTIONS are:

- critical functions:
 - placing and removing the HEARING AID;
 - fitting a HEARING AID;
 - testing of essential physical HEARING AID parameters;
- frequently used functions:
 - changing battery;
 - cleaning;
 - switching on/off;
 - adjust volume, program and other essential parameters;

NOTE See IEC 60601-1-6 for explanation of the term "frequently used functions".

201.12.4 Protection against hazardous output**201.12.4.2 Indication relevant to safety**

Subclause 12.4.2 of the general standard does not apply.

201.12.4.4 Incorrect output*Replacement:*

When a control adjusts the FITTED OSPL90, the FITTED OSPL90 shall not increase if the control is disconnected or defective.

Software controlled FITTED OSPL90 shall not exceed the selected value as a result of corrupt data transfer between programmer and HEARING AID.

See requirements in 201.9.6.

Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.

201.12.4.5 Diagnostic or therapeutic radiation

Subclause 12.4.5 of the general standard does not apply.

201.13 * HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.1.2 Emissions, deformation of ENCLOSURE or exceeding maximum temperature

Replacement:

The following HAZARDOUS SITUATIONS shall not occur:

- unintentional exposure to a SPL above the FITTED OSPL90;
- emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;
- deformation of ENCLOSURES to such an extent that compliance with 201.15.3.1 is impaired;
- temperatures of HEARING AIDS that are likely to be touched, exceeding 50 °C when measured and adjusted as described in 201.11.1.3;
- exceeding the allowable values for "other components and materials" identified in Table 22 of the general standard times 1,5 minus 12,5 °C.

The SINGLE FAULT CONDITIONS in 4.7 of the general standard with regard to the emission of flames, molten metal or ignitable substances shall not be applied to parts and components where:

- the construction of the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J;

Compliance shall be checked by drawing 15 W from the supply circuit for 1 min. If, after 1 min the supply circuit cannot supply 15 W, the circuit shall be considered to limit power dissipation to less than 15 W. The related design documentation is also reviewed.

or

- secondary circuits meet all of the following conditions:
 - they are mounted on material with a flammability classification of FV1 in accordance with IEC 60695-11-10 or better;
 - they are energized at a voltage of 60 V DC or 42,2 V peak or less in NORMAL and SINGLE FAULT CONDITION;
 - they are limited to 100 VA or are limited to 6 000 J in SINGLE FAULT CONDITION;
 - they employ wire insulation of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide;

Compliance is checked by evaluation of the design documentation.

or

- the component is a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS as described in 4.9 of the general standard;

Compliance is checked by evaluation of the design documentation.

or

- the components are completely contained within a fire enclosure according to 11.3 of the general standard.

After the tests of this subclause, thermal cut-outs and over-current releases shall be inspected to determine that their setting has not changed (by heating, vibration or other causes) sufficiently to affect their safety function.

201.13.2 SINGLE FAULT CONDITIONS

201.13.2.1 General

Replacement:

During the application of the SINGLE FAULT CONDITIONS listed in 201.13.2.2 to 201.13.2.13 (inclusive), the NORMAL CONDITIONS identified in a) shall also be applied in the least favourable combination.

a) NORMAL CONDITION includes all of the following simultaneously:

- the presence on any SIGNAL INPUT/OUTPUT PART of any voltage or current from other electrical equipment that is permitted to be connected according to the ACCOMPANYING DOCUMENTS as specified in 201.7.9;
- open circuit of any or all earth connections that do not comply with the requirements of 8.6 of the general standard, including any functional earth connection.

b) SINGLE FAULT CONDITION includes:

- short circuit of any one insulation that complies with the requirements for one MEANS OF PROTECTION as specified in 8.8 of the general standard;
NOTE This includes short circuiting of either constituent part of DOUBLE INSULATION that complies with 8.8 of the general standard.
- short circuit of any one CREEPAGE DISTANCE or AIR CLEARANCE that complies with the requirements for one MEANS OF PROTECTION as specified in 8.9 of the general standard;
- short circuit and open circuit of any component other than a COMPONENT WITH HIGH INTEGRITY CHARACTERISTICS that is connected in parallel with insulation, with an AIR CLEARANCE or with a CREEPAGE DISTANCE, unless shorting can be shown not to be a failure mode for the component (see also 4.8 and 4.9 of the general standard);
- open circuit of any one PROTECTIVE EARTH CONDUCTOR or internal PROTECTIVE EARTH CONNECTION that complies with the requirements of 8.6 of the general standard: this does not apply to a PROTECTIVE EARTH CONDUCTOR of PERMANENTLY INSTALLED ME EQUIPMENT, which is considered unlikely to become disconnected;
- interruption of any one power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES, if the RISK ANALYSIS indicates that this condition might cause permitted limits to be exceeded;
- unintended movement of a component; but only if the component is not mounted securely enough to ensure that such movement will be very unlikely to occur during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, as determined by the RISK MANAGEMENT PROCESS (see also 8.10.1 of the general standard);
- accidental detachment of conductors.

201.13.2.2 Electrical SINGLE FAULT CONDITION

Replacement:

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 201.13.2.1

201.13.2.3 Overheating of transformers in ME EQUIPMENT

Subclause 13.2.3 of the general standard does not apply, because HEARING AIDS do not have transformers.

201.13.2.4 Failure of THERMOSTATS

Subclause 13.2.4 of the general standard does not apply, because HEARING AIDS do not have THERMOSTATS.

201.13.2.5 Failure of temperature limiting devices

Subclause 13.2.5 of the general standard does not apply, because HEARING AIDS do not have temperature limiting devices.

201.13.2.7 Impairment of cooling that could result in a HAZARDOUS SITUATION

Subclause 13.2.7 of the general standard does not apply, because HEARING AIDS do neither depend on ventilation nor use cooling systems.

201.13.2.8 Locking of moving parts

Subclause 13.2.8 of the general standard does not apply, because HEARING AIDS do not have such moving parts.

201.13.2.9 Interruption and short circuiting of motor capacitors

Subclause 13.2.9 of the general standard does not apply, because HEARING AIDS do not have motors.

201.13.2.10 Additional test criteria for motor operated ME EQUIPMENT

Subclause 13.2.10 of the general standard does not apply, because HEARING AIDS do not have motors.

201.13.2.11 * Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS

Subclause 13.2.11 of the general standard does not apply.

201.13.2.12 Failure of parts that might result in a MECHANICAL HAZARD

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in Clause 201.9 and 201.15.3.

201.13.2.13 Overload

Subclause 13.2.13 of the general standard does not apply, because HEARING AIDS do not have motors or heating elements and cannot be overloaded.

201.14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard does not apply, except as follows:

201.14.1 General

Replacement:

Embedded and fitting software shall conform to IEC 62304.

The classification of software according to IEC 62304 shall be the result of the RISK ASSESSMENT.

Compliance shall be determined by application of the requirements in Clause 201.14 by inspection of the RISK MANAGEMENT FILE. Compliance with the IEC 62304 software design and the RISK MANAGEMENT PROCESS by inspection of external or internal audit reports or certificates.

NOTE Fitting software is usually classified and treated as a medical device.

201.14.2 Documentation

Subclause 14.2 of the general standard applies.

201.14.3 RISK MANAGEMENT plan

Subclause 14.3 of the general standard applies.

201.14.6 RISK MANAGEMENT PROCESS

201.14.6.1 Identification of known and foreseeable HAZARDS

Subclause 14.6.1 of the general standard applies.

201.14.11 PEMS validation

Subclause 14.11 of the general standard applies.

201.15 * Construction of ME EQUIPMENT

Clause 15 of the general standard does not apply, except as follows:

201.15.2 Serviceability

Replacement:

Parts of HEARING AIDS subject to mechanical wear, electrical and environmental degradation or ageing that could result in an unacceptable RISK if allowed to continue unchecked for too long a period shall be accessible for inspection, replacement and maintenance.

Compliance shall be checked by inspection of the parts mentioned above in this subclause and of their location.

201.15.3 Mechanical strength

201.15.3.1 General

Replacement:

HEARING AIDS or their parts shall have adequate mechanical strength and shall not result in loss of BASIC SAFETY due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.

For HEARING AID-related ACCESSORIES, IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards apply.

Mechanical design requirements for HEARING AIDS intended for use by infants under 36 months:

a) Battery doors shall be constructed to:

- require a tool to remove the battery; or

- require a force of at least 10 N in the least favourable direction to remove the battery.
- b) Any detachable part of the HEARING AID (e.g. ear hook, tube, type plate, programming cover) shall not be removable:
 - without a tool; or
 - with a force lower than 10 N in the direction of least resistance.

Compliance shall be checked by inspection of the product and the application of the described forces (see also 201.15.3.4).

201.15.3.4 Drop test

Replacement:

HEARING AIDS shall not result in an unacceptable RISK as a result of a free fall.

Compliance shall be checked by the following test.

The sample shall be tested, with any safe working load in place, by allowing it to fall freely, once from each of six different starting orientations from a height of 1,0 m onto a hard wood surface.

After the test, the HEARING AID shall not result in an unacceptable RISK, such as increased LEAKAGE CURRENT addressed in 201.8.7 or MECHANICAL HAZARDS see 201.9.

201.15.3.7 Environmental influences

Replacement:

The selection and treatment of materials used in the construction of HEARING AIDS shall take account of the INTENDED USE, the EXPECTED SERVICE LIFE and the conditions for transport and storage.

The HEARING AIDS shall be so designed and constructed that during its EXPECTED SERVICE LIFE any corrosion, ageing, mechanical wear, or degradation of biological materials due to the influence of moisture, sweat, humidity, hair care products or toiletries shall not reduce its mechanical properties in a way that results in an unacceptable RISK. See also 201.15.2.

Compliance shall be checked by inspection:

- of the HEARING AIDS, of the ACCOMPANYING DOCUMENTS and of the MANUFACTURER'S specifications of materials used and of the processing specifications for these materials;
- of the MANUFACTURER'S relevant tests or calculations.

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.3 Batteries

201.15.4.3.1 Housing

Replacement:

Battery compartments shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in a HAZARDOUS SITUATION.

If a HAZARDOUS SITUATION might develop by the incorrect connection or replacement of a battery, the equipment shall be fitted with a means of preventing incorrect polarity.

201.15.4.3.3 Protection against overcharging

Subclause 15.4.3.3 of the general standard applies.

Additional subclause:

201.15.4.3.101 HEARING AID batteries

Batteries used to supply HEARING AIDS shall comply with the relevant international standards. The design of the electronic circuit shall avoid overheating of the wrong inserted battery above 50 °C.

201.15.4.4 Indicators

Replacement:

HEARING AIDS do not require any indicators for the PATIENT.

For HEARING AID-related ACCESSORIES, IEC 60950-1, IEC 60065, IEC 62368-1 or the applicable relevant IEC standard applies.

201.16 * ME SYSTEMS

Replacement:

The voltage to earth or to ACCESSIBLE PARTS other than HEARING AIDS shall not exceed 42,4 V peak AC or 60 V DC in NORMAL CONDITION or in SINGLE FAULT CONDITION. The DC limit of 60 V applies to DC with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies. The power shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential of 2 V or more.

The voltage and energy limits specified above also apply to:

- internal parts, other than contacts of plugs, connectors and socket-outlets, that can be touched by the test pin shown in Figure 8 of the general standard inserted through an opening in an enclosure;
- internal parts that can be touched by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening in the top of an enclosure or through any opening provided for the adjustment of pre-set controls that may be adjusted by the PATIENT in NORMAL USE by using a tool.

Compliance shall be checked by inserting the test pin or the test rod through relevant openings.

The test pin shall be inserted in every possible position with minimal force (not more than 1 N).

The test rod shall be inserted in every possible position through openings provided for the adjustment of pre-set controls that can be adjusted by the PATIENT in NORMAL USE, in case of doubt with a force of 10 N.

If the instructions for use specify that a particular tool is to be used, the test is repeated with that tool.

NOTE All other system aspects are addressed in the individual clauses of this particular standard.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Replacement:

The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the introduction by the HEARING AID of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment and systems.

Electromagnetic compatibility shall be tested in accordance with IEC 60601-1-2. For HEARING AID additional testing for immunity to digital wireless interference shall be tested according to IEC 60118-13.

See Annex DD.

Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.

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Annexes

The annexes of the general standard apply, except as follows:

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Annex E
(informative)

**Examples of the connection of the measuring device (MD) for
measurement of the PATIENT LEAKAGE CURRENT and
PATIENT AUXILIARY CURRENT**

Annex E of the general standard does not apply.

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Annex G
(normative)

**Protection against HAZARDS of ignition of flammable
anaesthetic mixtures**

Annex G of the general standard does not apply.

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Annex H (informative)

PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation

Annex H of the general standard does not apply.

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Annex I (informative)

ME SYSTEMS aspects

Annex I of the general standard does not apply.

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Annex J
(informative)

Survey of insulation paths

Annex J of the general standard does not apply.

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Annex K (informative)

Simplified PATIENT LEAKAGE CURRENT diagrams

Annex K of the general standard does not apply.

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Annex L
(normative)

Insulated winding wires for use without interleaved insulation

Annex L of the general standard does not apply.

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Annex AA (informative)

Particular guidance and rationale

AA.1 General guidance

This document was created in order to fill a gap in standardization for HEARING AIDS.

HEARING AIDS have been considered inherently safe in the past. In order to fulfil regulatory requirements, MANUFACTURERS applied regulations directly by proprietary test specification based on RISK assessment and experience from trials or field data, as well as application of normative references. Due to a close cooperation of MANUFACTURERS in industrial associations, these requirements were in part coordinated and already standardized in the past. In order to create an industry standard to address regulatory requirements, an attempt was made in the 1990s, which resulted in CENELEC draft prEN 50220 in 1998. No positive voting was achieved and the European hearing instrument manufacturers association (EHIMA) released an industrial standard under its own name instead, with nearly identical content; however, this document has lacked broad acceptance. Consequently, EHIMA decided in 2009 to end this uncertainty and approached IEC with the request to produce an internationally accepted HEARING AIDS safety standard.

It is generally recognised by the HEARING AID industry and by regulators that IEC 60601-1 is not suitable to be applied to HEARING AIDS. For this reason, the HEARING AID industry has not been participating in the activities of IEC/TC 62 and its subcommittees previously. As a result, the specification of safety requirements for HEARING AIDS has developed in a fundamentally different way compared to IEC 60601-1. Therefore, the initial approach was to create a new IEC standard outside the IEC 60601 series. The task was assigned to TC 29 "Electroacoustics" and in particular its WG 13 "Hearing Aids" in which the stakeholders in the field of audiological technology are represented. TC 62 was approached with the request for assistance and suggested the integration of this document into the IEC 60601 series in order to be in line with the structures in IEC standardization. The fundamental difference in the approach safety specifications could be accommodated by the creation of a particular standard that provides for consideration of the individual requirements due to the particular application of the products in the scope. The integration of established HEARING AID safety requirements into the IEC 60601 series resulted in a relatively high number of replacements of parts of the general and collateral standards.

AA.2 Definition of safety requirements for HEARING AIDS

Due to the application and INTENDED USE of HEARING AIDS, the risks are in many cases not comparable with those of medical products typically covered by the scope of IEC 60601-1. This document represents current best practices in the HEARING AID industry. This document is based on MANUFACTURER'S RISK assessments, internal standards, field trials and the evaluation of reported and known incidents and long-term experience.

The OPERATOR and the PATIENT are one and the same due to the INTENDED USE of a HEARING AID in a HOME HEALTHCARE ENVIRONMENT.

Table AA.101 summarizes in short the approach of this document.

Table AA.101 – Summary of the approach of this document

Subject	Risk and requirements
Electrical	There is no electrical HAZARD due to an internal supply with low voltage and low energy (typically below maximum battery voltage specified by the HEARING AID MANUFACTURER and clearly within the limits of 201.8.4.2). A limit for accessible contacts at battery voltage was newly introduced in this document. Connection to external devices: Historically there are (representing the state of the art) connections to a) consumer products (audio input) or b) medical products (for programming) The RISK presented by using a HEARING AID is comparable with that of using an audio headphone. Requirements of IEC 60065 or IEC 60950-1 or IEC 62368-1 (or other where relevant) cover this RISK sufficiently. The RISK is extremely low, and no known incidents with HEARING AIDS or headphones have been reported. Warning: Connect only to compliant products. An additional LEAKAGE CURRENT test to provide a minimum insulation between audio input and user was newly introduced in this document. Acceptable without further requirements.
Mechanical	Sharp edges to be avoided (also after drop test). Requirements to avoid parts from remaining in the ear. Mechanical requirements and instructions to avoid small children from swallowing parts where applicable.
Radiation	None.
Biological, Chemical	Biocompatibility testing for materials in contact with the PATIENT. Warning regarding the expansion or leakage of batteries if charged incorrectly. Marking and constructional requirements to battery door.
Heat, fire	There is no unacceptable RISK due to an internal supply with low voltage and low energy. Fault tests in this document validate this aspect. Warning regarding the expansion or leakage of batteries if charged incorrectly. Marking and constructional requirements to battery door.
Acoustical	Fault tolerant design of hardware and software (PEMS requirements) as well as programming and wireless interfaces to avoid unintentional exposure to higher levels. EMC testing required. Indication of the FITTED OSPL90 on either the HEARING AID or the fitting software. Warning to the user and HEARING AID PROFESSIONAL for HEARING AIDS intentionally emitting more than 132 dB SPL.
Interference	EMC and radio testing. Warnings to user about special risks, like pace makers, aircraft or explosive environment.
USABILITY	Marking in blue/red on the HEARING AID to indicate left/right. USABILITY ENGINEERING and identification of PRIMARY OPERATING FUNCTIONS
ACCESSORY	1) Remote control and battery charger have risks comparable to IT or consumer goods (mobile phone, TV remote, etc.) and can therefore be covered sufficiently by the requirements of IEC 60065, IEC 60950-1 or IEC 62368-1 (or other where relevant). 2) Programming interfaces shall comply with IEC 60601-1. Alternative wireless programming interfaces may be covered by IEC 62368-1 or other applicable IEC safety standards.

AA.3 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document. The numbering is, therefore, not consecutive.

Clause 201.1.1 – Scope

In general, ACCESSORIES to HEARING AIDS like remote control units, audio streamers, battery chargers, power supplies and similar items are used in the same environment, by the same users as entertainment, IT or household products such as mobile phones, TV remote controls etc. For that reason, the risks of these product groups are comparable and requirements of IEC 60601 general and collateral standards are often unsuitable. The application of IEC 60950-1, IEC 60065, or IEC 62368-1 will, in conjunction with this document, cover the risks appropriately. ACCESSORY is in many cases designed and/or manufactured by manufacturers in the IT or audio/video sector who are more accustomed to these requirements. This is in line with the approach of IEC 60601-1-11.

In contrast, programming interfaces or ACCESSORIES in clinical applications are operated by HEARING AID PROFESSIONALS in a clinical environment and should therefore be covered by the general standard.

Clause 201.1.3 – Collateral standards

IEC 60601-1-9 has not been applied by the HEARING AID industry in the past. Compared to the ME EQUIPMENT traditionally in the scope of IEC 60601-1, HEARING AIDS have a very limited environmental impact. Since this subject is covered by local legislation sufficiently and the environmental impact is not directly related to the scope of BASIC SAFETY, it was decided to not apply this collateral standard and handle the subject outside of this document.

After a review of the IEC 60601-1-11 requirements, it became apparent that HEARING AIDS were not considered in the creation of this guideline resulting in a significant number of unsuitable requirements. It was deemed more feasible to consider the applicable aspects in the requirements of this particular standard rather than adopting IEC 60601-1-11 in general.

Subclause 201.5.9.1 – APPLIED PARTS

The term "APPLIED PART" was previously not in use in the HEARING AID community. The symbols for APPLIED PARTS are unknown to HEARING AID users and OPERATORS. A marking is not needed, since HEARING AIDS are always necessarily in touch with the PATIENT.

Subclause 201.7.8.1 – Colours of indicator lights

Low power consumption is essential in HEARING AID technology. The PATIENT should not be burdened with unacceptably frequent battery change cycles or unreasonable product dimensions due to large batteries. At the state of technology now and in foreseeable future, the use of any other colours than red for an indicator light (LED) is resulting in an unacceptable consumption of energy in a HEARING AID (background: voltage and current consumption are in direct correlation to the nature of the semi conductor material in use and as a result in direct correlation to the emitted wavelength/colour). For that reason, indicator lights are generally not required in this document and, if provided, the colour is not mandated. Indicator lights are in use, for example, in applications where PATIENTS may not express the loss of function due to young age or mental limitations. The colour red is indicating a critical situation only to personnel in clinical environment. The typical HEARING AID user is exposed to red lights in home, office and other environments, which reduces the need of harmonization with the colour requirements of the general standard.

Clause 201.8 – Protection against electrical HAZARDS from ME EQUIPMENT

There are no electrical hazards due to an internal supply with low voltage and low energy (typically 1,4 V to 4,5 V and energy clearly within the limits of 201.16).

Connection to external devices: Historically, there are (representing the state of the art) connections to a) consumer products (audio input) or b) medical products (for programming).

The RISK of a HEARING AID is comparable to an audio headphone. Electrical insulation requirements of IEC 60065, IEC 60950-1 or IEC 62368-1 (or other applicable standards where relevant) cover this RISK sufficiently. No incidents with HEARING AIDS or audio headphones have been reported. 201.7.9.2.5 requires an instruction to connect HEARING AIDS only to standard compliant products.

For these reasons, generally no insulation is required in a HEARING AID. Except in case of external connections to non-medical products, where an additional LEAKAGE CURRENT test between signal input and user is required in 201.8.7.

Accessible contacts at less than 4.5 V direct current of internally supplied HEARING AIDS were not regulated before publication of this document and did not result in harm or injury. Measurement results in worst case situation between contacts resulted in actual DC currents clearly below 10 μ A. A limit for PATIENT auxiliary circuits was introduced in 201.8.4.2.

Clause 201.9 – Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

MECHANICAL HAZARDS of HEARING AIDS are limited to the following items that are covered in this clause:

- sharp edges to be avoided (also after drop test);
- requirements to avoid parts from remaining in the ear (the 3 N requirement in 201.9.102 is derived from the extraction force of a HEARING AID);
- mechanical requirements and instructions to avoid small children from swallowing parts where applicable.

Subclause 201.9.6 – Acoustic energy (including infra- and ultrasound) and vibration

The maximum acceptable SOUND PRESSURE LEVEL, which does not cause discomfort or further hearing damage, depends on the individual uncomfortable loudness level (UCL).

During the fitting PROCESS, the maximum output level of the HEARING AID, in this document referred to as fitted maximum SOUND PRESSURE LEVEL (FITTED OSPL90), is adjusted as required by the individual (e.g. by HEARING AID PROFESSIONAL).

The FITTED OSPL90 is understood as the actual maximum output level at the end of the fitting.

In SINGLE FAULT CONDITION, the actual maximum output level may increase somewhat depending on the technical implementation, for example to keep sound distortion low in NORMAL CONDITION.

The indicated FITTED OSPL90 (e.g. in the fitting software) is derived by computation based on the settings of the HEARING AID and therefore may deviate from the actual level.

HEARING AIDS with output level 132 dB and above (measured according to IEC 60118-0, using a coupler according to IEC 60318-5) require labelling to make the HEARING AID PROFESSIONAL aware that SOUND PRESSURE LEVELS in this range also for a short period of time may cause hearing damage to those with normal hearing. The SPL on 132 dB in the coupler is equivalent to about 135 dB in free-field conditions at 1 kHz. The requirement for a warning for HEARING AIDS with a MAXIMUM OSPL90 of 132 dB or higher is derived from the FDA guidance 21 CFR 801.420. The value of 135 dB is also in agreement with the lower exposer action peak value of Article 3 of the Directive 2003/10/EC.

Clause 201.10 – Protection against unwanted and excessive radiation hazards

HEARING AIDS do not emit such radiation other than visible light in some cases.

Clause 201.11 – Protection against excessive temperatures and other HAZARDS

Usually, there is no unacceptable RISK of fire, heat or ignition due to an internal supply with low voltage and low energy. Most requirements of the general standard are therefore not applicable and temperature measurements are typically not required.

Subclause 201.12.2 – USABILITY of ME EQUIPMENT

Compared to the ME EQUIPMENT traditionally in the scope of IEC 60601-1, HEARING AIDS have very limited USABILITY aspects. Typical examples for PRIMARY OPERATING FUNCTIONS are listed here and might not apply. USABILITY ENGINEERING may also lead to further PRIMARY OPERATING FUNCTIONS.

Clause 201.13 – HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Due to the absence of electrical hazards, fire and heat hazards (see Annex AA clause 201.8 and 201.11), many requirements of this clause of the general standard are not applicable.

Subclause 201.13.2.11 – Failures of components in me equipment used in conjunction with oxygen rich environments

The requirements for HEARING AID that are intended to be used in explosive and oxygen enriched atmospheres are not contained in this particular standard.

Clause 201.14 – PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

In line with the low risks caused by HEARING AIDS compared to ME EQUIPMENT traditionally in the scope of IEC 60601-1, the software for HEARING AIDS is rather uncritical and of lower complexity. Historically, the HEARING AID industry has applied IEC 62304 and not IEC 60601-1-4². Since this approach is now established and has proven appropriate, it is not deemed necessary to follow the approach of the third edition of IEC 60601-1 to tailor and specify the IEC 62304 requirements.

Clause 201.15 – Construction of ME EQUIPMENT

Due to the absence of electrical hazards, fire and heat hazards (see Annex AA, Clauses 201.8 and 201.11), many requirements of this clause of the general standard are not applicable.

Clause 201.16 – ME SYSTEMS

This clause of the general standard was deemed too extensive to be applied to the few minor system aspects of HEARING AID SYSTEMS. All system aspects were addressed in the individual clauses of this particular standard instead, supporting an easier application of this document.

² The IEC 60601-1-4:1996 and its Amendment 1:1999 have been withdrawn. No new edition of that publication has been planned at the time of publication of this document.

Annex BB (informative)

Abbreviations

CD	Committee Draft (IEC document status)
EHIMA	European hearing instrument manufacturers association
FDA	Food and Drug Administration
LED	light emitting diode
ME	medical electrical
NSH	Nordic cooperation on disability
NWIP	New Work Item Proposal (IEC document status)
OSHA	Occupational Safety and Health Administration (USA)
PEMS	programmable electrical medical system
RECD	real ear to coupler difference

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Annex CC (informative)

Essential performance

After a careful consideration of the clauses within this document, it was decided that they all deal with BASIC SAFETY as defined in the general standard. MANUFACTURERS have the ability to identify functions of HEARING AIDS which are considered ESSENTIAL PERFORMANCE in accordance with their RISK MANAGEMENT PROCESS.

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Annex DD (informative)

Electromagnetic compatibility of ME EQUIPMENT

Electromagnetic compatibility shall be tested according to IEC 60601-1-2. Any RISK shall be evaluated by the RISK MANAGEMENT.

Additionally, for HEARING AIDS immunity to radiated EM fields, requirements as specified in IEC 60118-13 (for USA ANSI C63.19) apply.

Table DD.101 shows an example of applicable standards for HEARING AID specific setting for RF radiated emissions.

**Table DD.101 – Example of applicable standards for HEARING AID
specific setting for RF radiated emissions**

Phenomenon	Applicable standard for HOME HEALTHCARE ENVIRONMENT	Setting of HEARING AID during the test
Radiated RF emissions of HEARING AID	CISPR 11, Group 1, Class B	Reference test setting as per IEC 60118-0

The MANUFACTURER should determine the appropriate test settings and requirements for their product. Table DD.102 is an example that can be used to help determine HEARING AIDS specific test settings and requirements for BASIC SAFETY and minimum immunity performance requirements.

This example is not a recommendation or suggested guideline. Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.

Table DD.102 – Example of applicable tests

Phenomenon	Immunity test levels for HOME HEALTHCARE ENVIRONMENT	Setting of the HEARING AID during the test	Pass/fail criteria for BASIC SAFETY	Minimum performance requirement for HEARING AIDS without radio function
ELECTROSTATIC DISCHARGE	a Level 4: ±8kV contact; ±2 kV; ±4 kV; ±8kV; ±15 kV air	b Full-on gain, with OSPL90 reduced by at least 10 dB	c For all levels: The output level with 90 dB input level shall not increase by more than 6 dB after ESD exposure; degradation acceptable.	HEARING AID shall withstand without degradation: a) level 2 without user interaction ±4 kV contact; ±4 kV air b) level 3 with user interaction (e.g. restart HEARING AID) ±6 kV contact; ±2 kV; ± 4 kV; ±8 kV air
Power frequency magnetic fields (PFMF)	30 A/m 50 Hz or 60 Hz (test according to IEC 61000-4-8)	Reference test setting as per IEC 60118-0	e N/a	d IRIL_{PFMF} = overall output interference level minus HFA ≤ 55 dB
a Levels see IEC 61000-4-2. b In order to be able to detect a possible increase of output level, the OSPL90 shall be set to at least 10 dB lower than the OSPL90 prior to testing. c The output level with 90 dB input is measured before and after ESD exposure. d Approach is to be determined. e N/a, because no safety relevant failure expected (similar like exposure to radiated RF fields).				

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³ The IEC 60601-1-4:1996 and its Amendment 1:1999 have been withdrawn. No new edition of that publication has been planned at the time of publication of this document.

⁴ Under preparation. Stage at the time of publication: ISO/FDIS 80008-8:2019

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-66: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de correction auditive et des systèmes de correction auditive

AVANT-PROPOS

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Cette troisième édition annule et remplace la deuxième édition parue en 2015. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

- a) révision de la définition des PERFORMANCES ESSENTIELLES;
- b) révision de l'application de l'IEC 60601-1-2:2014 pour les perturbations électromagnétiques;

- c) correction de la tension utilisée pour les APPAREILS DE CORRECTION AUDITIVE de 1,6 V à 4,5 V;
- d) correction du niveau d'essai de chute de 1,5 m à 1,0 m;
- e) correction de la formulation de l'IEC 60601-2-66:2015.

Le texte de cette Norme internationale est issu des documents suivants:

FDIS	Rapport de vote
29/1023/FDIS	29/1030/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

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INTRODUCTION

En 1998, l'industrie des APPAREILS DE CORRECTION AUDITIVE représentée par l'Association européenne des fabricants d'instruments d'audition (EHIMA) a tenté d'établir une norme, avec pour objectif principal de fournir aux FABRICANTS un guide montrant la conformité à la Directive européenne 93/42/CEE Dispositifs médicaux.

Le résultat du vote CENELEC concernant ce projet de norme européenne prEN 50220 a été négatif et le document a été publié en tant que "norme EHIMA" en juin 1998 avec un contenu presque identique. L'EHIMA a conclu en 2009 que les exigences de cette norme n'étaient plus d'actualité et qu'il convenait de produire une norme acceptée au niveau international pour la sécurité des APPAREILS DE CORRECTION AUDITIVE, publiée par l'IEC ou l'ISO, pour démontrer la conformité aux exigences réglementaires.

La présente norme particulière modifie et complète l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, désignée ci-après par "norme générale".

Une recommandation générale et une justification relatives aux exigences de la présente norme particulière sont indiquées à l'Annexe AA. Il est considéré que la connaissance des raisons qui ont conduit à énoncer ces exigences non seulement facilite l'application correcte de la présente norme particulière, mais accélérera en son temps toute révision rendue nécessaire du fait de modifications dans la pratique clinique ou d'évolutions technologiques. Cependant, l'Annexe AA ne fait pas partie des exigences du présent document.

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APPAREILS ÉLECTROMÉDICAUX –

Partie 2-66: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de correction auditive et des systèmes de correction auditive

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale¹ s'applique, avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE des APPAREILS DE CORRECTION AUDITIVE et des SYSTEMES DE CORRECTION AUDITIVE, également appelés ci-après "APPAREILS EM" ou "SYSTEMES EM".

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS DE CORRECTION AUDITIVE, ou uniquement aux SYSTEMES DE CORRECTION AUDITIVE, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si ce n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS DE CORRECTION AUDITIVE et aux SYSTEMES DE CORRECTION AUDITIVE, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue des APPAREILS DE CORRECTION AUDITIVE ou des SYSTEMES DE CORRECTION AUDITIVE dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document, à l'exception de 201.7.9.2 et de 201.9.6.

NOTE Voir aussi 4.2 de la norme générale.

Les ACCESSOIRES des APPAREILS DE CORRECTION AUDITIVE dans l'ENVIRONNEMENT DE SOINS A DOMICILE (par exemple, unités de commande à distance, diffuseurs de flux audio, chargeurs de batteries, alimentations) peuvent être soumis aux essais selon la norme applicable IEC 60065, IEC 60950-1, IEC 62368-1 ou d'autres normes de sécurité IEC applicables. En variante, il est admis d'appliquer la norme générale. Les APPAREILS DE CORRECTION AUDITIVE n'ont pas de PARTIE RELIEE AU RESEAU destinée à être connectée au RESEAU D'ALIMENTATION à courant alternatif. La connexion au RESEAU D'ALIMENTATION d'un SYSTEME DE CORRECTION AUDITIVE est couverte par l'alimentation, le chargeur ou d'autres types d'ACCESSOIRES.

Les ACCESSOIRES à CONNEXION FONCTIONNELLE à un APPAREIL DE CORRECTION AUDITIVE peuvent former un SYSTEME D'APPAREIL DE CORRECTION AUDITIVE. Les ACCESSOIRES de l'APPAREIL DE CORRECTION AUDITIVE qui ne sont pas physiquement reliés à l'APPAREIL DE CORRECTION AUDITIVE en UTILISATION NORMALE ne sont pas considérés comme PARTIE APPLIQUEE, puisqu'ils ne participent pas directement à l'UTILISATION PREVUE de l'APPAREIL DE CORRECTION AUDITIVE.

Les interfaces de programmation sans fil sont couvertes par la norme applicable IEC 60065, IEC 60950-1, IEC 62368-1 ou d'autres normes de sécurité IEC applicables. En variante, il est admis d'appliquer la norme générale.

¹ La norme générale est l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*.

Les interfaces de programmation à connexion câblée à l'APPAREIL DE CORRECTION AUDITIVE sont couvertes par la norme générale.

NOTE Les parties amovibles des APPAREILS DE CORRECTION AUDITIVE, même si elles sont fournies séparément (par exemple, contours d'oreille, dômes, filtres anticérumen, etc.), ne sont pas considérées comme des ACCESSOIRES, mais comme des composants.

Le présent document ne s'applique pas:

- aux implants cochléaires ou autres APPAREILS DE CORRECTION AUDITIVE implantés;
- aux APPAREILS DE CORRECTION AUDITIVE à conduction osseuse;
- aux APPAREILS DE CORRECTION AUDITIVE de formation (c'est-à-dire les APPAREILS DE CORRECTION AUDITIVE de groupe, les dispositifs d'entraînement auditif, etc.);
- à l'application d'un APPAREIL DE CORRECTION AUDITIVE au mesurage des niveaux d'audition; l'IEC 60645-1 s'applique;
- aux systèmes fixes de boucles d'induction audiofréquences ou à leurs composants, tels que décrits dans l'IEC 60118-4 et l'IEC 62489-1;
- à la fonction de génération acoustique d'un masqueur d'acouphène.

Le présent document ne traite pas des essais applicables aux rayonnements RF volontaires des appareils sans fil (par exemple, puissance de sortie rayonnée maximale, largeur de bande de modulation, etc.).

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir des exigences particulières pour la SECURITE DE BASE des APPAREILS DE CORRECTION AUDITIVE et des SYSTEMES DE CORRECTION AUDITIVE tels qu'ils sont définis en 201.3.202 et en 201.3.203.

201.1.3 * Normes collatérales

Addition:

La présente norme particulière fait référence aux normes collatérales applicables énumérées à l'Article 2 de la norme générale et à l'Article 201.2 de la présente norme particulière.

L'IEC 60601-1-3, l'IEC 60601-1-9 et l'IEC 60601-1-10 ne s'appliquent pas. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles que publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales, en fonction de ce qui est approprié pour l'APPAREIL EM particulier à l'étude, et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, dans la présente norme particulière, le terme "norme générale" désigne l'IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012. Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et des paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe "201" (par exemple, 201.1 dans le présent document aborde le contenu de l'Article 1 de la norme générale) ou à celle de la norme collatérale applicable avec le préfixe "20x", où x est le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple, 202.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale sont précisées en utilisant les termes suivants:

"Remplacement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

"Addition" signifie que le texte de la présente norme particulière vient s'ajouter aux exigences de la norme générale ou de la norme collatérale applicable.

"Amendement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué dans le texte de la présente norme particulière.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans la norme générale sont numérotées de 3.1 à 3.147, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes supplémentaires sont appelées AA, BB, etc., et les points supplémentaires aa), bb), etc.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à la norme générale, à toutes les normes collatérales applicables et à la présente norme particulière considérées ensemble.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, bien que potentiellement non pertinent, s'applique sans modification; lorsqu'il est prévu qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que pertinente, ne s'applique pas, cela est expressément mentionné dans la présente norme particulière.

201.2 Références normatives

NOTE Une liste de références informatives est donnée dans la Bibliographie.

L'Article 2 de la norme générale s'applique, avec les exceptions suivantes:

Remplacement:

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

IEC 60950-1:2005, *Matériels de traitement de l'information – Sécurité – Partie 1: Exigences générales*

IEC 60950-1:2005/AMD1:2009

IEC 60950-1:2005/AMD2:2013

Addition:

IEC 60118-0:2015, *Électroacoustique – Appareils de correction auditive – Partie 0: Mesure des caractéristiques fonctionnelles des appareils de correction auditive*

IEC 60118-13, *Électroacoustique – Appareils de correction auditive – Partie 13: Compatibilité électromagnétique (CEM)*

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles.*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1-11:2015, *Appareils électromédicaux – Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles – Norme Collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile*

IEC 62368-1:2018, *Équipements des technologies de l'audio/vidéo, de l'information et de la communication – Partie 1: Exigences de sécurité*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC 60601-1 et l'IEC 60601-1:2005/AMD1:2012, ainsi que les suivants, s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse <http://www.electropedia.org/>
- ISO Online browsing platform: disponible à l'adresse <http://www.iso.org/obp>

NOTE Un index des termes définis est donné à partir de la page 114.

201.3.73

OPÉRATEUR

Addition:

Note 101 à l'article Correspond généralement au patient pour les APPAREILS DE CORRECTION AUDITIVE dans un ENVIRONNEMENT DE SOINS À DOMICILE.

201.3.76

PATIENT

Remplacement:

Note 1 à l'article: Dans la présente norme particulière et dans l'application des exigences de la norme générale, le terme PATIENT a la signification expliquée dans le deuxième alinéa de 4.1 de la norme générale. Le PATIENT est également, en général, l'OPÉRATEUR.

Le terme PATIENT est utilisé dans le présent document en conformité avec la terminologie usuelle dans le domaine des produits médicaux. Il est toutefois admis que l'utilisateur d'un APPAREIL DE CORRECTION AUDITIVE n'est généralement pas une personne malade, mais une personne en bonne santé malentendante dans un ENVIRONNEMENT DE SOINS À DOMICILE.

201.3.113

PERSONNEL D'ENTRETIEN

Remplacement:

personnes ou entité qui installent, entretiennent ou réparent les APPAREILS DE CORRECTION AUDITIVE ou les SYSTEMES DE CORRECTION AUDITIVE

201.3.132

PARTIE APPLIQUEE DE TYPE B

Remplacement:

PARTIE APPLIQUEE conforme aux exigences spécifiées de la présente norme particulière pour assurer une protection contre les chocs électriques, particulièrement en ce qui concerne le COURANT DE FUITE PATIENT admissible et le COURANT AUXILIAIRE PATIENT admissible

Addition:

201.3.201

AUDIOPROTHESISTE

personne compétente en audiologie qui évalue l'audition de façon professionnelle, sélectionne, adapte et fournit des SYSTÈMES DE CORRECTION AUDITIVE et des services de réhabilitation aux personnes malentendantes

201.3.202

APPAREIL DE CORRECTION AUDITIVE

APPAREIL EM, qui prélève le son et fournit le son traité au conduit auditif par conduction aérienne

Note 1 à l'article: Un APPAREIL DE CORRECTION AUDITIVE comprend toutes les parties amovibles qui sont essentielles pour la performance à laquelle il est destiné.

201.3.203

SYSTEME D'AUDITION

SYSTEME DE CORRECTION AUDITIVE

combinaison, telle qu'elle est spécifiée par son FABRICANT, d'éléments d'appareil, dont au moins un est un APPAREIL DE CORRECTION AUDITIVE destiné à être interconnecté par des CONNEXIONS FONCTIONNELLES spécifiées

201.3.204

NIVEAU DE PRESSION ACOUSTIQUE

SPL

L_p

dix fois le logarithme décimal du rapport de la valeur moyenne quadratique pondérée de la pression acoustique dans le domaine temporel, p , au carré d'une valeur de référence, p_0 , exprimé en décibels

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

où la valeur de référence, p_0 , est égale à 20 μPa

Note 1 à l'article : p^2 est considéré comme représentant le carré d'une pression acoustique pondérée dans le temps, limitée en bande de fréquences ou pondérée en fréquence.

Si des pondérations fréquentielles et temporelles spécifiques telles que celles définies dans l'IEC 61672-1 et/ou des bandes de fréquences spécifiques sont appliquées, il convient de l'indiquer au moyen d'indices appropriés; par exemple, $L_{p,AF}$ désigne le NIVEAU DE PRESSION ACOUSTIQUE pondéré A, avec pondération dans le temps F.

Note 2 à l'article: Cette définition est techniquement conforme à l'ISO/FDIS 80000-8:2019, 8-22.

Note 3 à l'article: L'abréviation "SPL" est dérivée du terme anglais développé correspondant "sound pressure level".

Note 4 à l'article: Tout NIVEAU DE PRESSION ACOUSTIQUE spécifié dans le présent document est mesuré en décibels (dB) comme décrit dans l'IEC 60118-0 à l'aide d'un coupleur conforme à l'IEC 60318-5.

[SOURCE: ISO/TR 25417:2007, 2.2 – L'article terminologique original existe en anglais et en russe uniquement.]

201.3.205**NIVEAU DE PRESSION ACOUSTIQUE DE SORTIE MAXIMAL****OSPL90 MAXIMAL**

SPL de sortie maximal d'un APPAREIL DE CORRECTION AUDITIVE mesuré avec un réglage maximal et pour un SPL d'entrée de 90 dB, comme défini dans l'IEC 60118-0

201.3.206**NIVEAU DE PRESSION ACOUSTIQUE DE SORTIE MAXIMAL ADAPTÉ****OSPL90 ADAPTÉ**

SPL de sortie maximal d'un APPAREIL DE CORRECTION AUDITIVE mesuré après adaptation et pour un SPL d'entrée de 90 dB

Note 1 à l'article: Puisque les paramètres des APPAREILS DE CORRECTION AUDITIVE ne sont pas complets, l'OSPL90 adapté est égal ou inférieur à l'OSPL90 maximal. Généralement l'OSPL90 est réalisé par le choix d'un APPAREIL DE CORRECTION AUDITIVE avec un OSPL90 maximal approprié et le réglage de précision de la sortie maximale.

201.4 Exigences générales

L'Article 4 de la norme générale s'applique, avec les exceptions suivantes:

201.4.1 Conditions d'application aux APPAREILS EM ou aux SYSTEMES EM

Remplacement:

Sauf spécification contraire, les exigences du présent document doivent s'appliquer en UTILISATION NORMALE et en cas de mauvais usage raisonnablement prévisible.

Lorsque le présent document est appliquée à des APPAREILS DE CORRECTION AUDITIVE ou à des SYSTEMES DE CORRECTION AUDITIVE, les définitions et les exigences qui utilisent le terme PATIENT doivent être considérées comme s'appliquant à la personne à laquelle est destiné l'APPAREIL DE CORRECTION AUDITIVE ou le SYSTEME DE CORRECTION AUDITIVE.

201.4.3 PERFORMANCE ESSENTIELLE

Addition:

Voir Annexe CC.

201.4.6 PARTIES D'APPAREIL EM ou de SYSTEME EM en contact avec le PATIENT

Le 4.6 de la norme générale ne s'applique pas.

201.4.10 Alimentation

Le 4.10 de la norme générale ne s'applique pas.

201.4.11 Puissance absorbée

Le 4.11 de la norme générale ne s'applique pas.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de la norme générale s'applique, avec les exceptions suivantes:

201.5.2 Nombre de spécimens

Remplacement:

Les ESSAIS DE TYPE sont effectués sur un spécimen représentatif de l'élément à l'étude. Si plusieurs produits qui ont une architecture mécanique et électrique similaire sont à l'étude, une analyse d'ingénierie effectuée par le FABRICANT peut alors justifier de n'utiliser qu'un seul spécimen représentatif pour une famille de produits.

201.5.3 Température ambiante, humidité, pression atmosphérique

Remplacement:

Après avoir mis les APPAREILS DE CORRECTION AUDITIVE ou les SYSTEMES DE CORRECTION AUDITIVE à soumettre aux essais en condition d'UTILISATION NORMALE, les essais sont effectués dans la plage des conditions d'environnement indiquée dans la description technique, comme spécifié par le FABRICANT.

201.5.4 Autres conditions

Addition:

- aa) Les conditions de conservation du stock sont spécifiées par le FABRICANT.
- bb) Les conditions de transport des APPAREILS DE CORRECTION AUDITIVE sont spécifiées par le FABRICANT.

201.5.5 Tensions d'alimentation, type de courant, nature de l'alimentation, fréquence

Remplacement:

- a) Si les résultats des essais sont influencés par des fluctuations de la tension d'alimentation par rapport à sa valeur assignée, les effets de ces fluctuations doivent être pris en considération.
- b) Les APPAREILS DE CORRECTION AUDITIVE et les SYSTEMES DE CORRECTION AUDITIVE, conçus pour fonctionner sous plus d'une tension assignée doivent être soumis à l'essai dans les conditions correspondant à la tension et à la nature de l'alimentation les moins favorables.
- c) Les APPAREILS DE CORRECTION AUDITIVE pour lesquels des ACCESSOIRES ou des parties amovibles interchangeables peuvent être connecté(e)s comme spécifié dans les DOCUMENTS D'ACCOMPAGNEMENT doivent être soumis à l'essai avec les ACCESSOIRES ou les parties amovibles qui entraînent les conditions les moins favorables.
- d) Si les instructions d'utilisation spécifient que l'APPAREIL DE CORRECTION AUDITIVE ou le SYSTEME DE CORRECTION AUDITIVE est destiné à recevoir son énergie d'une alimentation séparée, il doit être connecté à une telle alimentation.

201.5.7 Préconditionnement humide

Remplacement:

Lorsque les conditions climatiques sont susceptibles d'influencer la sécurité, l'APPAREIL DE CORRECTION AUDITIVE, le SYSTEME DE CORRECTION AUDITIVE ou leurs parties doivent être soumis à un preconditionnement humide avant les essais de 201.8.7.4.

L'APPAREIL DE CORRECTION AUDITIVE et le SYSTEME DE CORRECTION AUDITIVE ou leurs parties doivent être complètement montés (ou le cas échéant partiellement). Les protections utilisées pendant le transport et le stockage doivent être retirées.

Les parties amovibles sans outil doivent être détachées, mais sont soumises à l'essai en même temps que la partie principale.

Les CAPOTS D'ACCES qui peuvent être ouverts ou enlevés sans outil doivent être ouverts et enlevés.

Le préconditionnement humide doit être effectué dans une chambre humide contenant de l'air à un taux d'humidité relative de $93 \% \pm 3 \%$, où sont placés l'APPAREIL EM ou ses parties en essai. Les conditions d'humidité aux autres emplacements dans l'enceinte peuvent varier de $\pm 6 \%$. La température de l'air dans la chambre humide, à tous les endroits où les APPAREILS DE CORRECTION AUDITIVE et les SYSTEMES DE CORRECTION AUDITIVE peuvent être placés, doit être maintenue dans les limites de 2°C de toute valeur T appropriée dans la plage de $+20^{\circ}\text{C}$ à $+30^{\circ}\text{C}$. Avant de les introduire dans la chambre humide, les APPAREILS DE CORRECTION AUDITIVE et les SYSTEMES DE CORRECTION AUDITIVE sont amenés à une température comprise entre T et $T + 4^{\circ}\text{C}$ en les maintenant à cette température pendant au moins 4 h avant le début du traitement humide.

Maintenir les APPAREILS DE CORRECTION AUDITIVE et les SYSTEMES DE CORRECTION AUDITIVE et leurs parties, lorsque L'ENVELOPPE est classée IPX0, dans la chambre humide pendant au moins 48 h.

Maintenir les APPAREILS DE CORRECTION AUDITIVE et les SYSTEMES DE CORRECTION AUDITIVE et leurs parties, lorsque L'ENVELOPPE est conçue pour assurer une plus grande protection contre la pénétration de liquides, dans la chambre humide pendant 168 h.

201.5.9 Détermination des PARTIES APPLIQUEES et des PARTIES ACCESSIBLES

201.5.9.1 * PARTIES APPLIQUEES

Addition:

L'APPAREIL DE CORRECTION AUDITIVE est une PARTIE APPLIQUEE DE TYPE B dans le SYSTEME DE CORRECTION AUDITIVE. Si d'autres parties éventuelles doivent être en contact avec le PATIENT, ces parties sont également des PARTIES APPLIQUEES DE TYPE B.

201.5.9.2 PARTIE ACCESSIBLE

201.5.9.2.1 Doigt d'essai

Addition:

Les essais, tels que décrits dans la norme générale, sont en outre réalisés avec le petit calibre de doigt d'essai représenté à la Figure 1 de l'IEC 60601-1-11:2015.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de la norme générale s'applique, avec les exceptions suivantes:

201.6.2 Protection contre les chocs électriques

Remplacement:

Les APPAREILS DE CORRECTION AUDITIVE sont ALIMENTES DE MANIERE INTERNE, mais ils peuvent avoir des connexions à des appareils alimentés par le réseau. L'isolation par rapport au RESEAU D'ALIMENTATION d'un APPAREIL DE CORRECTION AUDITIVE doit être couverte par l'alimentation électrique, le chargeur ou un autre type d'ACCESSOIRE.

L'APPAREIL DE CORRECTION AUDITIVE est classé comme PARTIE APPLIQUEE DE TYPE B.

201.6.3 Protection contre les effets nuisibles de la pénétration d'eau ou de corps solides

Remplacement:

Voir 201.11.6.5.

201.6.6 Mode de fonctionnement

Remplacement:

Les APPAREILS DE CORRECTION AUDITIVE sont classés pour UN SERVICE CONTINU.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de la norme générale s'applique, avec les exceptions suivantes:

201.7.1 Généralités

201.7.1.1 APTITUDE A L'UTILISATION de l'identification, du marquage et de la documentation

Remplacement:

Le FABRICANT doit, dans le PROCESSUS DE GESTION DES RISQUES, traiter la question du RISQUE de mauvaise APTITUDE A L'UTILISATION associée à la conception de l'identification, du marquage et de la documentation des APPAREILS DE CORRECTION AUDITIVE.

L'APTITUDE A L'UTILISATION de l'identification, du marquage et des DOCUMENTS D'ACCOMPAGNEMENT destinés au PATIENT doit être évaluée sur la base d'un PROFIL DE PATIENT qui correspond à une formation scolaire élémentaire.

Il convient que les APPAREILS DE CORRECTION AUDITIVE soient conçus de manière à être simples d'utilisation et à ne pas exiger de référence à des DOCUMENTS D'ACCOMPAGNEMENT complexes.

La conformité doit être vérifiée par examen des résultats du PROCESSUS DE GESTION DES RISQUES.

201.7.1.2 Lisibilité des marquages

Remplacement:

Les marquages exigés par 7.2 et 7.3 doivent être CLAIREMENT LISIBLES dans les conditions suivantes:

- les signes de sécurité et l'identification, à l'exception du numéro de série, sur l'APPAREIL DE CORRECTION AUDITIVE lorsqu'il est placé dans la main du PATIENT, doivent être CLAIREMENT LISIBLES;
- le numéro de série et les autres marquages doivent être lisibles en utilisant une aide optique si nécessaire.

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM

201.7.2.1 Exigences minimales pour le marquage sur les APPAREILS EM et sur les parties interchangeables

Remplacement:

Si la taille de l'APPAREIL DE CORRECTION AUDITIVE ne permet pas l'inscription de tous les marquages spécifiés en 7.2, les marquages doivent être entièrement enregistrés dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.7.2.2 Identification

Remplacement:

Les APPAREILS DE CORRECTION AUDITIVE doivent porter à l'extérieur un marquage avec:

- le nom ou la marque de fabrique du FABRICANT;
- une REFERENCE DU MODELE OU DU TYPE.

Les APPAREILS DE CORRECTION AUDITIVE doivent porter à l'extérieur ou à tout autre emplacement accessible à l'utilisateur, de manière visible, un marquage avec:

- l'identification des APPAREILS DE CORRECTION AUDITIVE de gauche et de droite, sauf si l'absence de ce marquage ne présente pas un RISQUE inacceptable. La droite est définie par la couleur rouge. La gauche est définie par la couleur bleue;
- le numéro de série.

Dans le cas des APPAREILS DE CORRECTION AUDITIVE portés dans l'oreille, le marquage sur l'APPAREIL DE CORRECTION AUDITIVE peut être limité au numéro de série et à l'identification de la droite et de la gauche. Lorsque cela n'est pas possible, tous les renseignements pertinents à fournir sur l'étiquetage peuvent être apposés sur l'emballage de chaque appareil.

Les APPAREILS DE CORRECTION AUDITIVE doivent porter à l'extérieur ou à tout autre emplacement accessible à l'utilisateur, de manière visible, un marquage avec:

- l'année de fabrication.

Le numéro de série, l'identificateur de lot(s) et l'année de fabrication peuvent être fournis dans un code lisible par l'utilisateur ou par une technologie d'identification automatique telle que les codes à barres ou la RFID (identification par radio fréquence).

NOTE Voir l'ISO 15223-1 pour les symboles applicables au FABRICANT, au numéro de série, au lot, à l'année de fabrication et à la date limite d'utilisation.

201.7.2.5 APPAREILS EM destinés à être alimentés par d'autres appareils

Le 7.2.5 de la norme générale ne s'applique pas.

201.7.2.6 Raccordement au RESEAU D'ALIMENTATION

Le 7.2.6 de la norme générale ne s'applique pas.

201.7.2.7 Puissance absorbée du RESEAU D'ALIMENTATION

Le 7.2.7 de la norme générale ne s'applique pas.

201.7.2.8 Connecteurs de sortie

Le 7.2.8 de la norme générale ne s'applique pas.

201.7.2.10 PARTIES APPLIQUÉES

Le 7.2.10 de la norme générale ne s'applique pas.

201.7.2.17 Emballage de protection

Remplacement:

Si des mesures spéciales de manutention doivent être prises pendant le transport ou le stockage, l'emballage doit être marqué en conséquence.

201.7.8.1 * Couleurs des voyants lumineux

Remplacement:

Les couleurs des voyants lumineux et leur signification doivent être indiquées dans les instructions d'utilisation.

La conformité aux exigences est vérifiée par examen.

201.7.9 DOCUMENTS D'ACCOMPAGNEMENT

201.7.9.1 Généralités

Remplacement:

Les APPAREILS DE CORRECTION AUDITIVE doivent être accompagnés de documents comprenant au moins les instructions d'utilisation et une description technique. La description technique peut être incluse dans le même document que les instructions d'utilisation. Les DOCUMENTS D'ACCOMPAGNEMENT doivent être considérés comme faisant partie de L'APPAREIL DE CORRECTION AUDITIVE.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent identifier L'APPAREIL DE CORRECTION AUDITIVE en incluant, selon le cas, les éléments suivants:

- le nom ou la marque de fabrique du FABRICANT et les coordonnées auxquelles le PATIENT peut se référer;
- la RÉFÉRENCE DU MODÈLE OU DU TYPE;
- pour les APPAREILS DE CORRECTION AUDITIVE capables de produire un NIVEAU DE PRESSION ACOUSTIQUE supérieur à 132 dB: un avertissement à l'OPERATEUR professionnel adaptant l'APPAREIL DE CORRECTION AUDITIVE qu'il peut exister un RISQUE de détérioration de l'audition résiduelle du PATIENT.

Les DOCUMENTS D'ACCOMPAGNEMENT peuvent être fournis sur un support électronique, par exemple un fichier électronique qui peut être téléchargé par le public.

Si les DOCUMENTS D'ACCOMPAGNEMENT sont fournis sous forme électronique, le PROCESSUS D'INGENIERIE DE L'APTITUDE A L'UTILISATION doit définir quelles informations doivent également être fournies sur papier.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent être rédigés pour un niveau correspondant au niveau scolaire, à la formation et à tout besoin spécifique de la ou des personnes auxquelles ils sont destinés.

La conformité doit être vérifiée par examen des DOCUMENTS D'ACCOMPAGNEMENT, et, lorsque ceux-ci sont fournis sous forme électronique, comme spécifié dans l'IEC 60601-1-6.

201.7.9.2 Instructions d'utilisation

201.7.9.2.1 Généralités

Remplacement:

Les instructions d'utilisation doivent indiquer:

- le nom ou la marque de fabrique et l'adresse du FABRICANT;
- la REFERENCE DU MODELE OU DU TYPE;
- le but et l'UTILISATION PREVUE de l'APPAREIL DE CORRECTION AUDITIVE;
- les fonctions de service;
- l'identification de tous effets secondaires connus associés à l'utilisation de l'APPAREIL DE CORRECTION AUDITIVE qui peuvent justifier la consultation d'un médecin, par exemple une accumulation de cérumen.

Les instructions d'utilisation doivent être rédigées dans une langue compréhensible par le PATIENT prévu.

Les instructions d'utilisation doivent inclure

- des diagrammes, représentations ou photographies clairement compréhensibles de l'APPAREIL DE CORRECTION AUDITIVE complètement assemblé et prêt à fonctionner, y compris toutes les commandes, les signaux d'information visuels et les voyants lumineux;
- des diagrammes, représentations ou photographies clairement compréhensibles représentant la connexion correcte du PATIENT à l'APPAREIL DE CORRECTION AUDITIVE, aux ACCESSOIRES et aux autres appareils;
- toute éventuelle restriction relative aux emplacements ou environnements dans lesquels l'APPAREIL DE CORRECTION AUDITIVE peut être utilisé;
- une recommandation au PATIENT pour contacter le FABRICANT ou le représentant du FABRICANT:
 - pour obtenir une assistance, le cas échéant, dans le montage, l'utilisation ou l'entretien de l'APPAREIL DE CORRECTION AUDITIVE ou du SYSTEME DE CORRECTION AUDITIVE; ou
 - pour rendre compte d'un fonctionnement ou d'événements imprévus.

Les instructions d'utilisation doivent inclure une description et une représentation de la manière de remplacer et/ou de recharger les batteries.

201.7.9.2.2 Avertissement et consignes de sécurité

Remplacement:

Les instructions d'utilisation doivent inclure tous les avertissements et toutes les consignes de sécurité.

Il convient de placer les avertissements et les consignes de sécurité d'ordre général dans une section spécialement identifiée des instructions d'utilisation. Il convient qu'un avertissement ou une consigne de sécurité qui s'applique uniquement à une instruction ou une action spécifique précède l'instruction à laquelle il ou elle s'applique.

Selon le cas, les instructions d'utilisation doivent indiquer:

- pour les APPAREILS DE CORRECTION AUDITIVE utilisés dans les applications pédiatriques: un avertissement stipulant de maintenir hors de la portée des enfants les petites parties (APPAREILS DE CORRECTION AUDITIVE, batteries et parties amovibles) qui peuvent être avalées;

- pour les APPAREILS DE CORRECTION AUDITIVE qui ne sont pas conformes aux exigences pour les atmosphères explosives ou enrichies en oxygène: un avertissement stipulant de ne pas utiliser les APPAREILS DE CORRECTION AUDITIVE dans de telles zones;
- un avertissement selon lequel l'APPAREIL DE CORRECTION AUDITIVE spécifique ne doit être utilisé que par la personne prévue, et non par d'autres personnes;
- pour les APPAREILS DE CORRECTION AUDITIVE à transmission sans fil: un avertissement stipulant de vérifier, avant tout usage, le SYSTEME DE CORRECTION AUDITIVE dans des zones où les dispositifs électroniques ou sans fil sont limités;
- une indication exigée concernant les besoins spécifiques de groupes de PATIENTS particuliers, par exemple les jeunes enfants ou les personnes ayant un handicap mental;
- un avertissement concernant les conditions courantes susceptibles d'endommager l'APPAREIL DE CORRECTION AUDITIVE, telles qu'une chute, une immersion dans un liquide, des champs électromagnétiques forts ou une chaleur excessive;
- d'autres avertissements qui peuvent résulter de l'appréciation du RISQUE, par exemple un avertissement si des parties sont susceptibles de rester dans l'oreille et la conduite à tenir;
- les conditions environnementales admissibles de transport et de stockage d'un APPAREIL DE CORRECTION AUDITIVE après qu'il a été retiré de son emballage de protection et, par la suite, entre ses utilisations;
- pour chaque avertissement et indication de sécurité, la nature du DANGER, les conséquences susceptibles de se produire si le conseil n'est pas suivi, et les précautions permettant de réduire le RISQUE.

Avertissement à l'AUDIOPROTHÉSISTE:

- pour les APPAREILS DE CORRECTION AUDITIVE ayant un SPL de 132 dB ou un OSPL90 maximal supérieur;
- le SPL reçu par les oreilles des enfants peut être bien supérieur à celui reçu en moyenne par les adultes. Il est recommandé d'utiliser la RECD (différence entre l'oreille réelle et le coupleur) mesurée pour corriger la cible de l'OSPL90 adapté.

201.7.9.2.4 Source d'alimentation électrique

Remplacement:

Si une fuite provenant d'une batterie entraîne un RISQUE inacceptable, les instructions d'utilisation doivent inclure un avertissement demandant de retirer la batterie pour prévenir ce RISQUE.

Lorsque des batteries non amovibles sont utilisées, le FABRICANT doit en informer le PATIENT dans le manuel de l'utilisateur conformément au DOSSIER DE GESTION DES RISQUES.

201.7.9.2.5 Description de l'APPAREIL EM

Remplacement:

Les instructions d'utilisation doivent inclure

- une brève description de l'APPAREIL DE CORRECTION AUDITIVE;
- la manière dont l'APPAREIL DE CORRECTION AUDITIVE fonctionne.

Si l'APPAREIL DE CORRECTION AUDITIVE peut être connecté de manière externe, les instructions d'utilisation doivent formuler un avertissement de n'effectuer la connexion qu'à des appareils qui sont conformes aux normes de sécurité internationales appropriées.

201.7.9.2.9 Instructions de fonctionnement

Remplacement:

Les instructions d'utilisation doivent contenir toutes les informations nécessaires au fonctionnement de l'APPAREIL DE CORRECTION AUDITIVE conformément à sa spécification. Elles doivent comporter des explications concernant les fonctions des commandes, le compartiment de la batterie et les signaux, ainsi que la connexion et la déconnexion des parties amovibles par l'utilisateur et des ACCESSOIRES.

Les significations des symboles indicateurs de la gauche et de la droite, des indications d'avertissement, des abréviations et des voyants lumineux sur l'APPAREIL DE CORRECTION AUDITIVE doivent être expliquées dans les instructions d'utilisation.

201.7.9.2.12 Nettoyage, désinfection et stérilisation

Remplacement:

Les instructions d'utilisation doivent contenir les informations relatives au nettoyage et à la maintenance de l'APPAREIL DE CORRECTION AUDITIVE, le cas échéant:

- la procédure à suivre pour laver l'embout auriculaire;
- le remplacement des tubulures, filtres et autres parties remplaçables;
- le stockage de l'APPAREIL DE CORRECTION AUDITIVE;
- la maintenance appropriée particulière pour les batteries rechargeables;
- une information sur le lieu et la manière d'obtenir un service de réparation.

201.7.9.2.14 ACCESSOIRES, équipements supplémentaires, fournitures utilisées

Remplacement:

Les instructions d'utilisation doivent comprendre une liste des parties amovibles et remplaçables par l'utilisateur, ainsi que des ACCESSOIRES.

Si l'APPAREIL DE CORRECTION AUDITIVE est rechargeable, les instructions d'utilisation doivent au moins spécifier l'appareil de charge afin de garantir la conformité aux exigences du présent document.

201.7.9.2.15 Protection de l'environnement

Remplacement:

Les instructions d'utilisation doivent fournir les informations sur:

- la manière de mettre au rebut les batteries;
- la manière de mettre au rebut l'APPAREIL DE CORRECTION AUDITIVE;
- la manière de mettre au rebut toute partie qui peut présenter un RISQUE lié à sa mise au rebut.

201.7.9.2.16 Référence à la description technique

Remplacement:

Les instructions d'utilisation doivent contenir les informations spécifiées en 201.7.9.3 ou une référence à l'endroit où il faut trouver les éléments spécifiés en 201.7.9.3 (par exemple dans un manuel d'entretien).

La conformité aux exigences de 201.7.9.2 est vérifiée par examen des instructions d'utilisation rédigées dans une langue compréhensible pour le PATIENT prévu.

201.7.9.3 Description technique

201.7.9.3.1 Généralités

Remplacement:

La description technique doit fournir toutes les données qui sont essentielles à un fonctionnement, un transport et un stockage en toute sécurité.

Une fiche technique doit être à la disposition de l'OPERATEUR professionnel qui adapte l'APPAREIL DE CORRECTION AUDITIVE. La fiche technique doit comprendre:

- une brève description des caractéristiques physiques et de performance significatives de l'APPAREIL DE CORRECTION AUDITIVE;
- des caractéristiques techniques conformes à l'IEC 60118-0;
- un identificateur de version unique tel que sa date d'émission;
- un avertissement mettant en garde contre les DANGERS qui peuvent résulter d'une modification non autorisée des APPAREILS DE CORRECTION AUDITIVE, par exemple, un avertissement comme suit:
 - "AVERTISSEMENT: Modification de l'appareil interdite."
 - "AVERTISSEMENT: Interdiction de modification de cet appareil sans l'autorisation du fabricant."
 - "AVERTISSEMENT: Si l'appareil est modifié, un contrôle et un essai appropriés doivent être réalisés pour vérifier que l'appareil est toujours utilisable en toute sécurité."

201.8 * Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de la norme générale s'applique, avec les exceptions suivantes:

201.8.1 Règle fondamentale de protection contre les chocs électriques

Remplacement:

- a) Les APPAREILS DE CORRECTION AUDITIVE sont considérés comme sûrs s'ils sont alimentés par une source d'énergie interne.
- b) Les APPAREILS DE CORRECTION AUDITIVE avec des connexions externes à des appareils électromédicaux conformes à l'IEC 60601-1 et aux normes particulières applicables sont considérés comme sûrs.
- c) Les APPAREILS DE CORRECTION AUDITIVE qui sont généralement utilisés dans un ENVIRONNEMENT DE SOINS A DOMICILE sont considérés comme sûrs lorsqu'ils sont raccordés à des appareils électriques conformes à la norme pertinente IEC 60065, IEC 60950-1, IEC 62368-1, ou à d'autres normes de sécurité IEC applicables.

Les limites spécifiées en 201.8.4.2 ne doivent pas être dépassées pour les PARTIES ACCESSIBLES et les PARTIES APPLIQUEES en CONDITION NORMALE.

201.8.2.1 Connexion à une source électrique séparée

Remplacement:

Si un APPAREIL DE CORRECTION AUDITIVE est spécifié pour être connecté à une source électrique séparée autre que le RESEAU D'ALIMENTATION, la source électrique séparée doit être conforme à la norme pertinente IEC 60065, IEC 60950-1, IEC 62368-1, ou à d'autres normes de sécurité IEC applicables.

Si une source d'alimentation séparée particulière est spécifiée, alors l'essai pertinent doit être réalisé. Les APPAREILS DE CORRECTION AUDITIVE doivent y être connectés. Si une source d'alimentation séparée générique est spécifiée, alors la spécification des documents qui l'accompagnent doit être soumise à examen.

201.8.3 Classification des PARTIES APPLIQUÉES

Remplacement:

Un APPAREIL DE CORRECTION AUDITIVE est classé comme PARTIE APPLIQUÉE DE TYPE B.

201.8.4.2 PARTIES ACCESSIBLES incluant des PARTIES APPLIQUÉES

Remplacement:

- a) Les exigences de COURANT AUXILIAIRE PATIENT de la norme générale s'appliquent. Les contacts accessibles des APPAREILS DE CORRECTION AUDITIVE ALIMENTÉS DE MANIÈRE INTERNE avec une valeur assignée de 4,5 V courant continu ou moins sont exemptés de ces exigences tant que le courant continu circulant entre ces contacts dans la configuration réelle du cas le moins favorable ne dépasse pas 10 μ A et que l'appréciation du RISQUE couvre la conception et l'application spécifiques.
- b) Les APPAREILS DE CORRECTION AUDITIVE raccordés à des appareils électriques conformes à des normes autres que l'IEC 60601 doivent satisfaire aux exigences de COURANT DE FUITE décrites en 201.8.7.

201.8.5 Séparation des parties

Remplacement:

Voir 201.8.1.

201.8.7 COURANTS DE FUITE et COURANTS AUXILIAIRES PATIENT

201.8.7.1 Exigences générales

Remplacement:

- a) L'isolation électrique assurant la protection contre les chocs électriques doit être d'une qualité telle que les courants la traversant soient limités aux valeurs spécifiées en 201.8.7.3.
- b) Les valeurs spécifiées de ce COURANT DE FUITE s'appliquent pour toute combinaison des conditions suivantes:
 - à la température de fonctionnement et après le préconditionnement humide décrit en 201.5.7;
 - en CONDITION NORMALE;
 - avec les APPAREILS DE CORRECTION AUDITIVE alimentés en attente et en fonctionnement.

201.8.7.2 CONDITIONS DE PREMIER DEFAUT

Le 8.7.2 de la norme générale ne s'applique pas.

201.8.7.3 Valeurs admissibles

Remplacement:

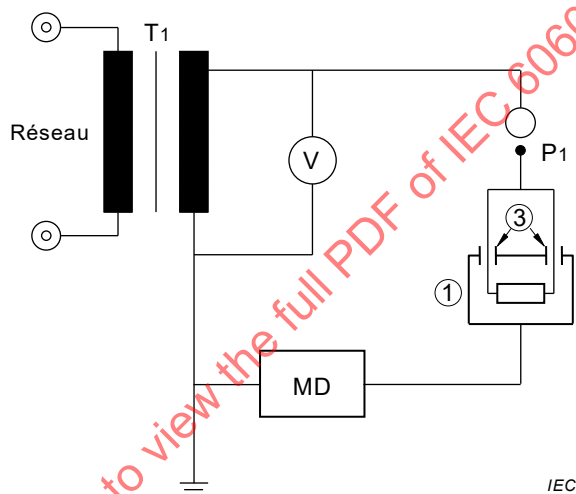
La valeur admissible pour le COURANT DE FUITE PATIENT est de 100 μ A en valeur efficace. Cette valeur s'applique au courant circulant dans le réseau de la Figure 12 de la norme générale et mesuré comme indiqué à la Figure 201.101. La tension de sortie nominale du transformateur de séparation est une tension alternative de 275 V à une fréquence de 50 Hz ou 60 Hz.

201.8.7.4 Mesures

201.8.7.4.1 Généralités

Remplacement:

Le COURANT DE FUITE PATIENT doit être mesuré après avoir amené L'APPAREIL DE CORRECTION AUDITIVE à sa température de fonctionnement.



Légende

- 1 enveloppe d'APPAREIL DE CORRECTION AUDITIVE
- 3 ENTREE/SORTIE DE SIGNAL court-circuitée ou chargée
- P₁ connexion externe
- T₁ transformateurs de séparation monophasés ou polyphasés ayant une puissance assignée suffisante et une tension de sortie réglable (voir aussi la justification de 8.7.4.2 de la norme générale).
- V voltmètre indiquant la valeur efficace, en utilisant, le cas échéant et si possible, un seul appareil avec un commutateur
- MD dispositif de mesure (voir la Figure 12 de la norme générale)

Figure 201.101 – Circuit de mesure pour COURANT DE FUITE (voir 201.8.7.4.7)

201.8.7.4.6 Mesure du COURANT DE CONTACT

Remplacement:

Le présent paragraphe est couvert par les exigences de 201.8.7.4.7.

201.8.7.4.7 Mesure du COURANT DE FUITE PATIENT

Remplacement:

L'APPAREIL DE CORRECTION AUDITIVE est soumis aux essais conformément à la Figure 201.101 à 110 % de la tension de réseau spécifiée la plus élevée, en utilisant le circuit d'alimentation de mesure approprié.

Pour les APPAREILS DE CORRECTION AUDITIVE qui ont une ENVELOPPE ou une partie de l'ENVELOPPE constituée d'un matériau isolant, une feuille métallique de 20 cm × 10 cm au maximum est appliquée en contact étroit avec l'ENVELOPPE ou la partie appropriée de l'ENVELOPPE.

La feuille métallique doit être déplacée, si possible, pour permettre de déterminer la valeur la plus élevée du COURANT DE FUITE PATIENT.

Les parties métalliques de l'ENVELOPPE peuvent être recouvertes partiellement ou totalement par la feuille métallique.

Il n'est pas nécessaire de réaliser le présent essai s'il peut être démontré qu'il y a une séparation appropriée des parties impliquées.

201.8.7.4.8 Mesure du COURANT AUXILIAIRE PATIENT

Addition:

Les contacts accessibles des APPAREILS DE CORRECTION AUDITIVE ALIMENTÉS DE MANIÈRE INTERNE à la tension assignée maximale de la batterie spécifiée par le FABRICANT d'APPAREILS DE CORRECTION AUDITIVE sont exemptés de ces exigences tant que le courant continu circulant entre ces contacts dans la configuration réelle du cas le moins favorable ne dépasse pas 10 µA et que l'appréciation du RISQUE couvre la conception et l'application spécifiques.

201.8.8 ISOLATION

Remplacement:

L'essai conforme au 8.7 de la norme générale doit être réalisé après l'essai de chute de 201.15.3.4.

201.8.9 LIGNES DE FUITE et DISTANCES DANS L'AIR

Le 8.9 de la norme générale ne s'applique pas.

201.8.10 Composants et câblage

Le 8.10 de la norme générale ne s'applique pas.

201.8.11 PARTIES RELIÉES AU RESEAU, composants et montage

Le 8.11 de la norme générale ne s'applique pas.

201.9 * Protection contre les DANGERS MECANQUES des APPAREILS EM et SYSTEMES EM

L'Article 9 de la norme générale s'applique, avec les exceptions suivantes:

201.9.1 DANGERS MECANQUES des APPAREILS EM

Remplacement:

Les APPAREILS DE CORRECTION AUDITIVE avec ACCESSOIRES n'entraînent généralement pas de dangers mécaniques. Le Tableau 201.101 ci-dessous donne une liste des dangers qui doivent être pris en considération.

Tableau 201.101 – DANGERS MECANQUES à prendre en considération

DANGER MÉCANIQUE	Couvert par le paragraphe
Arêtes vives	201.9.3
Énergie acoustique	201.9.6
Enchevêtrement	201.9.101
Parties restant dans le conduit auditif	201.9.102

201.9.2 DANGERS associés aux parties en mouvement

Le 9.2 de la norme générale ne s'applique pas.

201.9.3 DANGER associé aux surfaces, angles et arêtes

Remplacement:

Les surfaces rugueuses, les angles vifs et les arêtes des APPAREILS DE CORRECTION AUDITIVE et des SYSTEMES DE CORRECTION AUDITIVE, qui peuvent provoquer une blessure ou un dommage, doivent être évités ou recouverts.

Une attention particulière doit être accordée aux arêtes moulées, aux couvercles des batteries et aux brides des connecteurs.

La conformité doit être vérifiée par examen des APPAREILS DE CORRECTION AUDITIVE ou des SYSTEMES DE CORRECTION AUDITIVE.

201.9.4 DANGERS d'instabilité

Le 9.4 de la norme générale ne s'applique pas.

201.9.5 DANGER de projections de pièces

Le 9.5 de la norme générale ne s'applique pas.

201.9.6 * Énergie acoustique (y compris infra-et ultrasons) et vibrations

Remplacement:

Les APPAREILS DE CORRECTION AUDITIVE doivent être conçus de sorte que les utilisateurs ne puissent pas être involontairement exposés à un NIVEAU DE PRESSION ACOUSTIQUE (SPL) supérieur au NIVEAU DE PRESSION ACOUSTIQUE de sortie OSPL90 adapté en CONDITION NORMALE.

L'augmentation acceptable du niveau en CONDITION DE PREMIER DEFAUT doit être évaluée dans le DOSSIER DE GESTION DES RISQUES.

L'OSPL90 adapté doit être indiqué soit sur l'APPAREIL DE CORRECTION AUDITIVE soit sur le logiciel d'adaptation ou autrement. L'écart maximal doit être évalué dans le DOSSIER DE GESTION DES RISQUES.