BS EN 60601-2-66:2013

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-2-66:2013. It is identical to IEC 60601-2-66:2012.

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

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

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-66

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English version

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

(IEC 60601-2-66:2012)

Appareils électromédicaux -
Partie 2-66: Exigences particulières pour la sécurité de base et les performances essentielles des instruments d'audition et systèmes d'audition
(CEI 60601-2-66:2012)

Medizinische elektrische Geräte -
Teil 2-66: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hörgeräten und Hörgerätesystemen
(IEC 60601-2-66:2012)

This European Standard was approved by CENELEC on 2012-11-06. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-66:2013 E

Foreword

The text of document 29/777/FDIS, future edition 1 of IEC 60601-2-66, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-66:2013.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2013-08-06
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2015-11-06

This standard is to be read in conjunction with EN 60601-1:2006.

In this standard, 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 standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “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.

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-66:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60118-4:2006	NOTE	Harmonised as EN 60118-4:2006 (not modified).
IEC 60318-5:2006	NOTE	Harmonised as EN 60318-5:2006 (not modified).
IEC 60601-1-4:1996	NOTE	Harmonised as EN 60601-1-4:1996 (not modified).
IEC 60645-1:2001	NOTE	Harmonised as EN 60645-1:2001 (not modified).
IEC 61672-1:2002	NOTE	Harmonised as EN 61672-1:2003 (not modified).
IEC 62489-1:2010	NOTE	Harmonised as EN 62489-1:2010 (not modified).
ISO 80000-8:2007	NOTE	Harmonised as EN ISO 80000-8:2007 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

Annex ZA of EN 60601-1:2006 applies, except as follows:

In Annex ZA of EN 60601-1:2006 ***replace*** *the introductory paragraph by the following:*

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

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

Publication	Year	Title	EN/HD	Year
In Annex ZA of EN 60601-1:2006 ***replace*** *IEC 60950-1:2001 by:*				
IEC 60950-1 (mod) + corr. August	2005 2006	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1 + AC:2011 + A11 + A12	2006 2011 2009 2011
Add *to Annex ZA of EN 60601-1:2006 the following new references:*				
IEC 60065 (mod) + corr. August	2001 2002	Audio, video and similar electronic apparatus - Safety requirements	EN 60065 + corr. August + A11 + A12	2002 2007 2008 2011
IEC 60118-7	2005	Electroacoustics - Hearing aids - Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes	EN 60118-7	2005
IEC 60118-13	-	Electroacoustics - Hearing aids - Part 13: Electromagnetic compatibility (EMC)	EN 60118-13	-
IEC 60601-1-11 + corr. April	2010 2011	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	EN 60601-1-11	2010
IEC 62304	-	Medical device software - Software life-cycle processes	EN 62304	-
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EU Directive 93/42/EEC except the following:

– Essential Requirements 1 to 7.1
– Essential Requirement 7.4
– Essential Requirement 7.5, Paragraphs 2 and 3
– Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

INTRODUCTION

In 1998 the HEARING INSTRUMENT industry represented by the 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 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 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.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY of HEARING INSTRUMENTS and HEARING INSTRUMENT 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 only, or to HEARING INSTRUMENT 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 and to HEARING INSTRUMENT SYSTEMS, as relevant.

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

NOTE See also 201.4.2. (RISK MANAGEMENT).

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

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

This standard does not apply to:

– cochlear implants or other implanted HEARING INSTRUMENTS;

– bone conduction HEARING INSTRUMENTS;

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

– educational HEARING INSTRUMENTS (i.e. group HEARING INSTRUMENTS, auditory trainers etc.);
– the application of a HEARING INSTRUMENT for the measurement of hearing levels. IEC 60645-1 applies;
– 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.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY requirements for HEARING INSTRUMENTS and HEARING INSTRUMENT 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.

IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-9, 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 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 standard 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, additional definitions in this standard 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 standard" 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

Clause 2 of the general standard applies except as follows:

Replacement of the introductory paragraph:

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

NOTE Informative references are listed in the bibliography.

Replacement:

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

Addition:

IEC 60065:2001, *Audio, video and similar electronic apparatus –Safety requirements*

IEC 60118-7:2005, *Electroacoustics – Hearing aids – Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes*

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

IEC 60601-1-11:2010, *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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

NOTE An index of defined terms is found beginning on page 41.

201.3.73
OPERATOR

Addition:

Note 1 to entry: Usually equal to patient for hearing instruments in a home healthcare environment

201.3.76
PATIENT

Addition:

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 standard in line with the general terminology in the medical product field. It is however understood, that the user of a HEARING INSTRUMENT 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 or HEARING INSTRUMENT 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

201.3.202
HEARING INSTRUMENT
HEARING AID
ME EQUIPMENT which picks up sound and delivers processed sound to the ear canal through air-conduction. A HEARING INSTRUMENT includes all detachable parts that are essential for the performance of its intended use.

201.3.203
HEARING SYSTEM
HEARING INSTRUMENT SYSTEM
combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is a HEARING INSTRUMENT to be inter-connected by FUNCTIONAL CONNECTION

201.3.204
SOUND PRESSURE LEVEL
SPL
L_p

ten times the logarithm to the base 10 of the ratio of the square of the sound pressure, p, to the square of a reference value, p_0, expressed in decibels

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

where the reference value, p_0, is 20 μPa

[SOURCE: ISO/TR 25417:2007, 2.2]

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 80000-8:2007, 8-22.

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 standard shall apply in NORMAL USE and reasonably foreseeable misuse.

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

201.4.3 * ESSENTIAL PERFORMANCE

Replacement:

HEARING INSTRUMENTS do not have an ESSENTIAL PERFORMANCE.

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 or HEARING INSTRUMENT 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 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 and HEARING INSTRUMENT 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 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 or a HEARING INSTRUMENT 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 or HEARING INSTRUMENT SYSTEM or its parts, it shall be subjected to a humidity preconditioning treatment prior to the tests of 201.8.7.4.

HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS or theirs 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% ± 3%. The temperature of the air in the cabinet, at all places where HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS can be located, shall be maintained within 2 °C of any convenient value T in the range of + 20 °C to + 32 °C. Before being placed in the humidity cabinet, HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS shall be brought to a temperature between T and T + 4 °C, and kept at this temperature for at least 4 h before the humidity treatment.

HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS and its parts shall be kept in the humidity cabinet for at least 48 h.

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

201.5.9.1 *APPLIED PARTS

Addition:

The HEARING INSTRUMENT is a TYPE B APPLIED PART in the HEARING INSTRUMENT 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.

201.5.201 SOUND PRESSURE LEVEL

Any sound pressure level specified in this document is measured in decibels (dB) as described in IEC 60118-7:2005.

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

The HEARING INSTRUMENT 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 are classified for CONTINUOUS OPERATION.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.1.1 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 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 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 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

Replacement:

If the size of the HEARING INSTRUMENT 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 shall be marked on the outside with:

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

HEARING INSTRUMENTS shall be marked visibly on the outside or inside when the battery drawer is open, with:

– identification of right and left HEARING INSTRUMENT 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 worn in the ear, the marking on the instrument may be reduced to the serial number and the identification of right and left.

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 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.

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

– name or trade-name of the MANUFACTURER and an address to which the PATIENT can refer;
– model or type reference.

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. electronic file format on CD-ROM.

If the ACCOMPANYING DOCUMENTS are provided electronically, the RISK MANAGEMENT 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.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Replacement:

The instructions for use shall document:

– the purpose and INTENDED USE of the HEARING INSTRUMENT;
– the operating functions;
– identification of any known side effects associated with the use of hearing instrument that may warrant consultation with a physician e.g. 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 including all controls, visual information signals, and indicators;
– easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the HEARING INSTRUMENT, ACCESSORIES and other equipment;
– any restrictions on locations or environments in which the HEARING INSTRUMENT 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 or HEARING INSTRUMENTS 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.

NOTE 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 in pediatric applications: warning to keep small parts (HEARING INSTRUMENTS, batteries and detachable parts) that can be swallowed out of children's reach;
– for HEARING INSTRUMENTS able to provide more than 132 dB SPL: warning to the professional OPERATOR fitting the HEARING INSTRUMENT that there may be a RISK of impairing the remaining hearing of the PATIENT;
– for HEARING INSTRUMENTS that do not comply with requirements for explosive or oxygen-enriched atmospheres: warning not to use the HEARING INSTRUMENT in such areas;
– warning that the specific HEARING INSTRUMENT must only be used by the intended person and not by others;
– for HEARING INSTRUMENTS with wireless transmission: warning to check first before using the HEARING SYSTEM in areas where electronics or wireless devices are restricted;
– statement required about the special needs of particular PATIENT groups e.g. small children or mentally disabled persons;
– warning about common conditions that could damage the HEARING INSTRUMENT such as dropping, immersing in liquid, strong electromagnetic fields or excessive heat;
– other warnings that may result from the risk assessment, e.g. 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 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.

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.

201.7.9.2.5 ME EQUIPMENT description

Replacement:

The instructions for use shall include:

– a brief description of the HEARING INSTRUMENT;
– how the HEARING INSTRUMENT operates.

If the HEARING INSTRUMENT 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 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 detachable parts and ACCESSORIES.

The meanings of left and right indicator symbols, warning statements, abbreviations and indicator lights on the HEARING INSTRUMENT 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 where applicable:

– the procedure to follow for washing the ear mould;
– replacing tubing, filters and other replaceable parts;
– storing the HEARING INSTRUMENT;
– 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 detachable and replaceable parts as well as ACCESSORIES.

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

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;
– 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. The data sheet shall include:

– a brief description of the HEARING INSTRUMENT'S significant physical and performance characteristics;
– technical characteristics according to IEC 60118-7.

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 are considered safe if supplied by an internal power source since they are well within the limits of 201.8.4.2.
b) HEARING INSTRUMENTS with external connections to medical electrical equipment in compliance with IEC 60601-1 and the applicable particular standards are considered safe.
c) HEARING INSTRUMENTS 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. 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 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, 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 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 is classified as a TYPE B APPLIED PART.

201.8.4.2 ACCESSIBLE PARTS including APPLIED PARTS

Replacement:

a) The requirements to PATIENT AUXILIARY CURRENT of the general standard apply. Accessible contacts of internally supplied HEARING INSTRUMENTS rated at 1,6 V d.c. or less are exempt from these requirements as long as the d.c. current flowing in a realistic worst case configuration between those contacts does not exceed 10μA and the risk assessment covers the particular design and application.
b) HEARING INSTRUMENTS 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 5.7;

– in NORMAL CONDITION;

– with HEARING INSTRUMENTS 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:

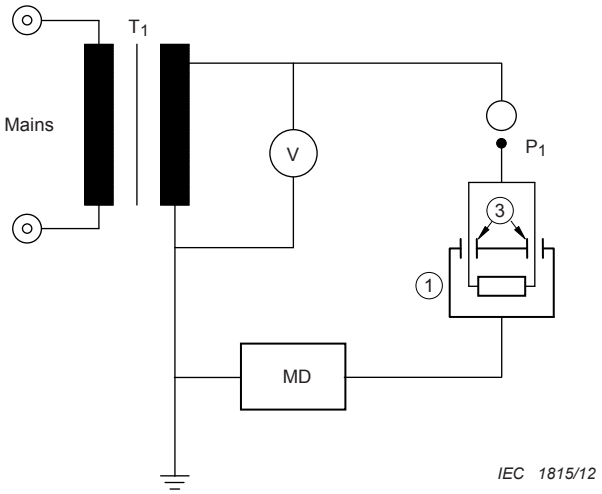
The allowable value of PATIENT LEAKAGE CURRENT is 100 μA rms. This value applies to current flowing through the network of Figure 12 of the general standard and measured as shown in Figure 201.101. The nominal output voltage from the isolation transformer is 275 V a.c. at 50 Hz or 60 Hz.

201.8.7.4 Measurements

201.8.7.4.1 General

Replacement:

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



Legend

1 Hearing instrument 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 r.m.s 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 the 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 is tested according to Figure 201.101 at 110% of the highest specified mains voltage, using the appropriate measuring supply circuit.

For hearing instruments that have an enclosure or a part of the enclosure made of insulating material, metal foil of maximum 20 cm x 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 rated at 1,6 V d.c. or less are exempt from these requirements as long as the d.c. 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 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 with ACCESSORIES do not pose mechanical hazards. The table below lists hazards that shall be considered.

Table 201.102 – 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 HAZARDS associated with moving parts

Subclause 9.2 of the general standard does not apply.

201.9.3 HAZARD associated with surfaces, corners and edges

Replacement:

Rough surfaces, sharp corners and edges of HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS that could result in an unacceptable RISK 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 or HEARING INSTRUMENT SYSTEMS and the RISK MANAGEMENT FILE.

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.

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 do not have such parts.

201.9.8 HAZARDS associated with support systems

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

Additional subclauses:

201.9.101 HAZARD of entanglement

Cables and lanyards of HEARING INSTRUMENTS 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 30 N.

Compliance shall be checked by applying the pull force.

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

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

HEARING INSTRUMENTS 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 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 subclause 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:

201.11.1.1 Maximum temperature during NORMAL USE

Replacement:

The maximum temperature of the HEARING INSTRUMENT 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.

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, 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 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.*

201.11.2 Fire prevention

Subclause 11.2 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.

201.11.3 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 SYSTEM

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 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 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 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 and HEARING INSTRUMENTS 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 and HEARING INSTRUMENTS SYSTEMS, and their parts and ACCESSORIES and assure that no unacceptable RISK will occur. The results of the evaluation shall be documented in the RISK MANAGEMENT FILE.

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

Addition:

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

– critical functions:
  - placing and removing the HEARING INSTRUMENT;
  - fitting a HEARING INSTRUMENT;

- testing of essential physical HEARING INSTRUMENT 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".

201.12.4.2 Indication of parameters 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, output power shall not increase if the control is disconnected or defective. Software controlled maximum power settings shall not exceed the selected value as a result of corrupt data transfer between programmer and HEARING INSTRUMENT.

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

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;
– 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 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 or 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

– they are completely contained within a fire enclosure according to clause 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 13.2.2 to 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, 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;

   NOTE This includes short circuiting of either constituent part of DOUBLE INSULATION that complies with 8.8.

   – 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;
   – 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);
   – open circuit of any one PROTECTIVE EARTH CONDUCTOR or internal PROTECTIVE EARTH CONNECTION that complies with the requirements of 8.6: 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);
   – 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 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 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 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 HAZARD

Subclause 13.2.7 of the general standard does not apply, because HEARING INSTRUMENTS 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 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 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 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 9 and 15.3.

201.13.2.13 Overload

Subclause 13.2.13 of the general standard does not apply, because HEARING INSTRUMENTS do not have motors or heating elements and can't 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 201.14.2 to 14.13 (inclusive), by inspection of the RISK MANAGEMENT FILE. Compliance with the IEC 62304 software design process shall be by inspection of external or internal audit reports or certificates.

NOTE 1 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 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 or their parts shall have adequate mechanical strength and shall not result in an unacceptable RISK due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.

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

Mechanical design requirements for instruments 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 (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 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 m onto a hard wood surface.

After the test, the HEARING INSTRUMENT 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 shall take account of the INTENDED USE, the EXPECTED SERVICE LIFE and the conditions for transport and storage.

The HEARING INSTRUMENTS 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 15.2.

Compliance shall be checked by inspection:

– *of the HEARING INSTRUMENTS, 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.

201.15.4.3.101 HEARING INSTRUMENT batteries

Batteries, used to supply HEARING INSTRUMENTS, 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 do not require any indicators for the PATIENT.

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

201.16 *ME SYSTEMS

Replacement:

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

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 of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment and systems.

Electromagnetic compatibility is 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.

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

Annexes

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

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.

Annex G
(normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

Annex G of the general standard does not apply.

Annex H
(informative)

PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation

Annex H of the general standard does not apply.

Annex I
(informative)

ME SYSTEMS aspects

Annex I of the general standard does not apply.

Annex J
(informative)

Survey of insulation paths

Annex J of the general standard does not apply.

Annex K
(informative)

Simplified PATIENT LEAKAGE CURRENT diagrams

Annex K of the general standard does not apply.

Annex L
(normative)

Insulated winding wires for use without interleaved insulation

Annex L of the general standard does not apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 Rationale and background

This standard was created in order to fill a gap in standardization for HEARING INSTRUMENTS.

HEARING INSTRUMENTS have been considered inherently safe in the past. In order to fulfill 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 safety standard.

It is generally recognised by the HEARING INSTRUMENT industry and by regulators that IEC 60601-1 is not suitable to be applied to HEARING INSTRUMENTS. For this reason the HEARING INSTRUMENT 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 developed in a fundamentally different way compared to IEC 60601. 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 it’s 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 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

Due to the application and INTENDED USE of HEARING INSTRUMENTS, the risks are in many cases not comparable with those of medical products typically covered by the scope of IEC 60601. This document represents current best practices in the HEARING INSTRUMENT industry. This standard 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 in a HOME HEALTHCARE ENVIRONMENT.

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

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

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 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 is comparable with that of using an audio headphone. Requirements of IEC 60065 or IEC 60950 (or other where relevant) cover this risk sufficiently. The risk is extremely low, and no known incidents with HEARING INSTRUMENTS 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. Warning to the user and health care professional for instruments intentionally emitting more than 132 dB.
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 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 or IEC 60950 (or other where relevant). 2) Programming Interfaces shall comply with IEC 60601.

AA.3 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Clause 201.1.1 – Scope

In general ACCESSORIES to HEARING INSTRUMENTS 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 like 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, IEC 60065, or in future IEC 62368, 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 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 industry in the past. Compared to the ME EQUIPMENT traditionally in the scope of IEC 60601, HEARING INSTRUMENTS 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 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 community. The symbols for APPLIED PARTS are unknown to HEARING INSTRUMENT users and operators. A marking is not needed, since HEARING INSTRUMENTS 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 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 then red for an indicator light (LED) is resulting in an unacceptable consumption of energy in a HEARING INSTRUMENT (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 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 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 is comparable to an audio headphone. Electrical insulation requirements of IEC 60065 or IEC 60950 (or other applicable standards where relevant) cover this risk sufficiently. No incidents with HEARING INSTRUMENTS or audio headphones have been reported. 201.7.9.2.5. Requires an instruction to connect HEARING INSTRUMENTS only to standard compliant products.

For these reasons generally no insulation is required in a HEARING INSTRUMENT. 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 V d.c. of internally supplied HEARING INSTRUMENTS 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 d.c. 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 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);
– mechanical requirements and instructions to avoid small children from swallowing parts where applicable.

Subclause 201.9.6 – Acoustic energy

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).

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.

Clause 201.12 – USABILITY

Compared to the ME EQUIPMENT traditionally in the scope of IEC 60601, HEARING INSTRUMENTS 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

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.

Clause 201.14 – PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

In line with the low risks caused by HEARING INSTRUMENTS compared to ME EQUIPMENT traditionally in the scope of IEC 60601, the software for HEARING INSTRUMENTS is rather uncritical and of lower complexity. Historically the HEARING INSTRUMENT industry has applied IEC 62304 and not IEC 60601-1-4. Since this approach is now established and has proven appropriate, it is not deemed necessary to follow the approach of IEC 60601, 3rd edition, 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 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

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.

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 Safety and Health Administration (USA)
PEMS	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM

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Index of defined terms used in this particular standard

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