ICS 11.180.15, 17.140.50 SLOVENSKÁ TECHNICKÁ NORMA Júl 2020

STN	**Zdravotnícke elektrické prístroje Časť 2-66: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti prístrojov pre nedoslýchavých a zostáv prístrojov pre nedoslýchavých**	**STN EN IEC 60601-2-66** 36 4800

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/20

Obsahuje: EN IEC 60601-2-66:2020, IEC 60601-2-66:2019

Oznámením tejto normy sa od 19.02.2023 ruší
STN EN 60601-2-66 (36 4800) z júla 2016

131030

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-66

April 2020

ICS 11.180.15; 17.140.50

Supersedes EN 60601-2-66:2015 and all of its amendments and corrigenda (if any)

English Version

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems (IEC 60601-2-66:2019)

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 (IEC 60601-2-66:2019)

Medizinische elektrische Geräte - Teil 2-66: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hörgeräten und Hörgerätesystemen (IEC 60601-2-66:2019)

This European Standard was approved by CENELEC on 2020-02-19. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 29/1023/FDIS, future edition 3 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 IEC 60601-2-66:2020.

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) 2020-11-19
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-02-19

This document supersedes EN 60601-2-66:2015 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC 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 60601-2-66:2019 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 60118-4:2014	NOTE	Harmonized as EN 60118-4:2015 (not modified)
IEC 60318-5:2006	NOTE	Harmonized as EN 60318-5:2006 (not modified)
IEC 60601-1-9	NOTE	Harmonized as EN 60601-1-9
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10
IEC 60645-1:2017	NOTE	Harmonized as EN 60645-1:2017 (not modified)
IEC 61000-4-2	NOTE	Harmonized as EN 61000-4-2
IEC 61000-4-8	NOTE	Harmonized as EN 61000-4-8
IEC 62489-1:2010	NOTE	Harmonized as EN 62489-1:2010 (not modified)
IEC 62489-1:2010/A1:2014	NOTE	Harmonized as EN 62489-1:2010/A1:2015 (not modified)
IEC 62489-1:2010/A2:2017	NOTE	Harmonized as EN 62489-1:2010/A2:2018 (not modified)
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified)
CISPR 11	NOTE	Harmonized as EN 55011

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

Clause 2 of the general standard applies except as follows:

Replacement:

Publication	Year	Title	EN/HD	Year
IEC 60950-1 (mod)	2005	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1	2006
-	-		+ A11	2009
+ A1 (mod)	2009		+ A1	2010
-	-		+ A12	2011
+ A2 (mod)	2013		+ A2	2013
IEC 62368-1 (mod)	2014	Audio/video, information and communication technology equipment - Part 1: Safety requirements	EN 62368-1	2014
-	-		+ A11	2017

Addition:

Publication	Year	Title	EN/HD	Year
IEC 60118-0	2015	Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids	EN 60118-0	2015
IEC 60118-13	-	Electroacoustics - Hearing aids - Part 13: Electromagnetic compatibility (EMC)	EN 60118-13	2019
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
+ A1	2012		+ A1	2013
-	-		+ A12	2014

EN IEC 60601-2-66:2020 (E)

Publication	Year	Title	EN/HD	Year
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	EN 60601-1-2	2015
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	EN 60601-1-11	2015
IEC 62304	-	Medical device software - Software life cycle processes	EN 62304	2006
			+ A1	2015

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European standard has been prepared under a Commission's standardisation request M/023 and M432 concerning the development of European Standards related to medical devices given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of the EU Directives 93/42/EEC as amended by 2007/47/EC.

General Guidance:

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 This standard is intended to be applied in its entirety only. Selected clauses or subclauses may be not applicable due to the specific type of equipment under consideration. It is necessary to understand and apply Clauses 1 to 5. It is also recommended to understand and apply those clauses which contain general requirements related to a specific subclause. Elements of the standard that are not cited in Table ZZ.1 may be relevant for the appropriate fulfilment of certain essential requirements through indirect reference, and for safety and performance aspects of the device, that are not addressed through essential requirements.

NOTE 2 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance to the MDD (Directive 93/42/EEC amended by 2007/47/EC). This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 3 With respect to Note 4 of 4.2.2 General requirement for risk management, the manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 4 References in the Clauses 3 to 17 or in the Annexes of this standard specify whether the normative references listed in Clause 2 as cited in Annex ZA are to be applied in whole or in part.

NOTE 5 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

NOTE 6 According to the scope of this standard the coverage in Table ZZ.1 only applies to the design and construction of HEARING AIDS and HEARING AID SYSTEMS. This European Standard lists in Table ZZ.1 only the essential requirements covered.

WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

Table ZZ.1 – Relationship between Essential Requirements of Directive 93/42/EEC amended by 2007/47/EC, and clauses and subclauses of this standard

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	**Remarks/Notes**
1, second indent	201.7.9.1 201.7.9.2.1 201.7.9.2.2	This document (201.7.9.1, 201.7.9.2.1, 201.7.9.2.2) covers requirements related to instructions for use, including safety warnings and notices by considering the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).
5	201.7.2.17 201.7.9.2.2 201.15.3 201.15.3.7	Covered by requirements to design and packaging (201.7.2.17) to withstand transport and storage with regards of mechanical strength (201.15.3), resistance to environmental conditions (201.15.3.7) and the necessary instructions (201.7.9.2.2).
6	201.7.9.2.1 201.9.6	The reduction of unintentional exposure to excessive acoustic noise is covered in 201.9.6 regarding the design. 201.7.9.2.1 covers information and instructions for the user related to side effects.
7.1, first indent	201.11.1.1 201.13.1.2	Covered for risks of fire and high temperatures.
7.3	201.11.6.6 201.15.3.7	This document covers (201.15.3.7, 201.11.6.6) the design of devices in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures. Requirements for HEARING AIDS that are intended to be used in explosive and oxygenenriched atmospheres are not contained in this standard (see 201.11.2).
7.5, first sentence of first paragraph only	201.7.9.2.4	Covered for the risk of leakage from the battery in situ.
7.6	201.11.6.5	Covered in 201.11.6.5.
8.1, first sentence only	201.7.9.2.12 201.11.6.6 201.12.2	Design covered in 201.12.2, 201.11.6.6 and instruction covered in 201.7.9.2.12.
9.1	201.5.5 c) 201.6.2 201.7.9.2.5 201.7.9.2.9 201.8.1 201.8.2.1 201.8.4.2	

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	**Remarks/Notes**
9.2, first indent	201.9	Mechanical risks (e.g. 'entanglement') are covered by 201.9.
9.2, second indent	201.5.3 201.5.7 201.7.2.17 201.7.9.2.1 201.7.9.2.2 201.15.3.7	Covered in respect of environmental temperatures, humidity or variations in pressure: 201.5.3, 201.5.7, 201.7.2.17, 201.7.9.2.1, 201.7.9.2.2, 201.15.3.7 of this document provide design and test requirements with regards to climatic environmental conditions which are suitable to remove or minimize as far as possible these risks.
9.2, third indent	201.7.9.2.2 201.17	To fully cover this ER, risks must be removed or minimised as far as possible.
9.2, fourth indent	201.15.2	Covered for the serviceability of hearing aids subject to mechanical wear, electrical degradation or ageing.
9.3	201.11.1.1 201.13.1.2	Risks of fire and high temperatures covered in 201.11.1.1, 201.13.1.2. HEARING AIDS are normally not exposed to flammable substances or to substances which could cause combustion. The requirements for HEARING AIDS that are intended to be used in explosive and oxygenenriched atmospheres are not covered in this document.
12.5	201.17	To fully cover this ER, risks must be removed or minimised as far as possible.
12.6	201.8 201.13	Electrical risks covered in 201.8 for normal conditions and 201.13 in fault conditions.
12.7.1	201.15.3.1	Covered by the mechanical requirements in 201.15.3.1.
12.7.3	201.7 201.9.6 201.13.1.2	The reduction of unintentional exposure to excessive acoustic noise is covered in 201.9.6 regarding the design, in 201.7 regarding correct application 201.13.1.2 in case of faults.
12.7.4	201.8.1 201.8.2.1 201.8.7 201.16	Covered in respect of the following: Electrical Risks: 201.8.1 Fundamental rule of protection against electric shock 201.8.2.1 Connection to power sources 201.16 Limitation of voltage current or energy 201.8.7 Leakage current. Gas or hydraulic and pneumatic energy supplies not applicable to HEARING AIDS.
12.7.5	201.11.1	Covered by 201.11.1 Excessive temperatures

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Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	**Remarks/Notes**
12.8.1	201.9.6 201.12.4.4	Requirements of sufficient accurate indication of output is covered in 201.9.6. 201.12.4.4 covers possible sources of incorrect output.
12.8.2	201.9.6	The reduction of unintentional exposure to excessive acoustic noise is covered in 201.9.6
12.9	201.7.9.1 201.7.9.2.1 201.7.9.2.9	Requirements to specification of function of controls and indicators on the device or in the instructions for use are covered in 201.7.9.2.1 and 201.7.9.2.9.
13.1 – first and second paragraph	201.7.9.2 201.7.9.2.16	Covered in respect of the following: 201.7.9.2 Instructions for use. 201.7.9.2.16 Technical description, provided that the technical description is included in the instructions for use.
13.1 - first and third paragraph	201.7.2.2 201.7.2.17 201.7.9.2	Covered in respect of information on the packaging in 201.7.2.17. Covered in respect of information in the instruction for use in 201.7.9.2.
13.1 - first and fourth paragraph	201.7.9.2	Requirements for instruction for use covered in 201.7.9.2.
13.2	201.7.8.1 201.7.9.2.9	Description of symbols in the documentation covered in 201.7.9.2.9. Description of colours in the documentation covered in 201.7.8.1.
13.3 a)	201.7.2.2	To fully cover this ER, the name and address of the authorised representative must be provided, if applicable.
13.3 d)	201.7.2.2	To fully cover this ER the batch number (if provided) must be preceded by the symbol LOT.
13.3 i)	201.7.2.17	
13.3 j)	201.7.2	
13.3 l)	201.7.2.2	
13.4	201.7.9.1	Covered for the Instructions for Use.
13.5	201.7.2.2	Serial number required in 201.7.2.2.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	**Remarks/Notes**
13.6 b)	201.7.9.3	Covered provided the technical description is included in the instructions for use.
13.6 d)	201.7.9.2.1 201.7.9.2.12	
13.6 k)	201.7.9.2.1	
13.6 l)	201.7.9.2.1	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

IEC 60601-2-66

Edition 3.0 2019-10

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

IEC 60601-2-66:2019-10(en-fr)

IEC 60601-2-66

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INTERNATIONAL STANDARD

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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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.180.15; 17.140.50

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
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.

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.

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.

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 standard[1] 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.

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[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*