ICS 11.180.15, 17.140.50 SLOVENSKÁ TECHNICKÁ NORMA Júl 2016

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 60601-2-66** 36 4800

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument 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. 06/16

Obsahuje: EN 60601-2-66:2015, IEC 60601-2-66:2015

Oznámením tejto normy sa od 31.07.2018 ruší
STN EN 60601-2-66 (36 4800) z augusta 2013

122799

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-66

November 2015

ICS 11.180.15; 17.140.50

Supersedes EN 60601-2-66:2013

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 60601-2-66:2015)

Appareils électromédicaux - Partie 2-66: Exigences particulières pour la sécurité de base et les performances essentielles des instruments d'audition et systèmes d'audition
(IEC 60601-2-66:2015)

Medizinische elektrische Geräte - Teil 2-66: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hörgeräten und Hörgerätesystemen
(IEC 60601-2-66:2015)

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

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

European foreword

The text of document 29/851/FDIS, future edition 2 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 60601-2-66:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-05-27
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-07-31

This document supersedes EN 60601-2-66:2013.

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 60601-2-66:2015 was approved by CENELEC as a European Standard without any modification.

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

IEC 60118-4:2014	NOTE	Harmonized as EN 60118-4:2015 (not modified).
IEC 60318-5:2006	NOTE	Harmonized as EN 60318-5:2006 (not modified).
IEC 60601-1-4:1996	NOTE	Harmonized as EN 60601-1-4:1996 (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 60645-1:2012	NOTE	Harmonized as EN 60645-1:2015 (not modified).
IEC 62489-1:2010	NOTE	Harmonized as EN 62489-1:2010 (not modified).
ISO 80000-8:2007	NOTE	Harmonized as EN ISO 80000-8:2007 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

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

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

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

Publication	Year	Title	EN/HD	Year
Replacement:				
IEC 60950-1 (mod)	2005	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1 +AC	2006 2011
			+A11	2009
+A1 (mod)	2009		+A1	2010
			+A12	2011
+A2 (mod)	2013		+A2	2013
Addition:				
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	-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March	2006 2010
+A1	2012		+A1 +A1/AC	2013 2014
			+A12	2014

EN 60601-2-66:2015

Publication	Year	Title	EN/HD	Year
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	-
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 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 INSTRUMENTS or HEARING INSTRUMENT 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

No.	Essential Requirements	Coverage of EN 60601-2-66
I.	**GENERAL REQUIREMENTS**	
1	General Guidance note 2 and 3 shall be observed	
1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include:	The application of EN 60601-2-66 and the documents referenced in there (below referenced as “this document” or “this standard”) support a manufacturer to design HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS (below “devices”) in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, while accepting only risks associated with their intended use that constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. Details and exclusions supporting this general statement follow in order of the essential requirements below. Where the intended use of devices exceeds the scope of this document, the manufacturer may need to apply additional methods to achieve conformity to the essential requirements. Manufacturing aspects are not covered by this document! This statement applies to several essential requirements below but will not be repeated at each line, in order to provide for a better usability of this document.
	– reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	The application of this document (201.7.1.1, 201.12.2 with reference to EN 62366) reduces, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used.

No.	Essential Requirements	Coverage of EN 60601-2-66
	– consideration of 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).	This document (201.7.9.1, 201.7.9.2.2) puts consideration of 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).
2	General Guidance note 2 and 3 shall be observed	
2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:	The requirements of this document for the design and construction of the devices conform to safety principles, taking account of the generally acknowledged state of the art at the time it has been released (2014). This document references EN ISO 14971, the application of which (4.3) does provide for the coverage of potential developments and new conclusions in hearing aid safety that became known after the release of this particular standard. The requirements of this document have been established by selecting the most appropriate solutions to the particular devices and their risks, by applying the following principles in the following order:
	– eliminate or reduce risks as far as possible (inherently safe design and construction),	
	– where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	
	– inform users of the residual risks due to any shortcomings of the protection measures adopted.	
3	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	The performance aspect (clinical evaluation) is not covered by this document unless basic safety is concerned. HEARING INSTRUMENTS do not have ESSENTIAL PERFORMANCE (201.4.3). 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.

No.	Essential Requirements	Coverage of EN 60601-2-66
4	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	A failure of characteristics of HEARING INSTRUMENTS could not affect the clinical conditions and safety of the patients and other persons (201.4.3). 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.
5	General Guidance note 2 and 3 shall be observed	
5	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	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	General Guidance note 2 and 3 shall be observed	
6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	The requirements of this document are sufficient to keep risks to an acceptable level when weighed against the performances intended. This document also references EN ISO 14971, the application of which requires the criteria for acceptable risks (3.2). In general, HEARING INSTRUMENTS do not have side-effects beyond convenience issues. 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.
6a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	The performance aspect (clinical evaluation) is not covered by this document unless basic safety is concerned.
II.	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**	
7	**Chemical, physical and biological properties**	General Guidance note 2 and 3 shall be observed
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the ‘General requirements’. Particular attention must be paid to:	See section I and the details in the three indents below.

No.	Essential Requirements	Coverage of EN 60601-2-66
	– the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	Covered in respect of the toxicity: 11.7 Biocompatibility, the manufacturer should apply the appropriate part of the EN ISO 10993 series. Flammability: Risks of fire and high temperatures covered in 201.11.1.1, 201.13.1.2.
	– the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,	Covered in respect of the biocompatibility: 11.7 the manufacturer should apply the appropriate part of the EN ISO 10993 series.
	– where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	Such modelling research is not applicable to HEARING INSTRUMENTS.
7.2	The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	Covered in respect of the biocompatibility: 11.7 the manufacturer should apply the appropriate part of the EN ISO 10993 series.
7.3	The devices must be designed and manufactured 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;	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. The requirements for HEARING INSTRUMENTS that are intended to be used in explosive and oxygen-enriched atmospheres are not contained in this standard (201.11.2).
	if the devices are intended to administer medicinal products, they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	HEARING INSTRUMENTS are not intended to administer medicinal products.
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.	Not applicable to HEARING INSTRUMENTS.

No.	Essential Requirements	Coverage of EN 60601-2-66
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.	Covered by a warning in 201.7.9.2.4.
	Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.	HEARING INSTRUMENTS do not contain such substances.
	If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.	HEARING INSTRUMENTS are not intended to administer medicinal products.
	If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	HEARING INSTRUMENTS are not intended to administer medicinal products.
7.6	Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	Covered in 201.11.6.5
8	**Infection and microbial contamination**	General Guidance note 2 and 3 shall be observed
8.1	The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	Design covered in 201.12.2, 201.11.6.6 and instruction covered in 201.7.9.2.12.
8.2	Tissues of animal origin must originate from animals that have been subject to veterinary controls and surveillance adapted to the intended use of the tissues.	Not applicable to HEARING INSTRUMENTS.
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	Not applicable to HEARING INSTRUMENTS.

No.	Essential Requirements	Coverage of EN 60601-2-66
8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	Not applicable to HEARING INSTRUMENTS.
8.5	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	Not applicable to HEARING INSTRUMENTS.
8.6	Packaging system for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination;	Aspects of packaging not covered.
	the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	Not applicable to HEARING INSTRUMENTS.
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	Not applicable to HEARING INSTRUMENTS.
9	**Construction and environmental properties**	General Guidance note 2 and 3 shall be observed
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices.	Covered by 201.5.5, 201.7.9.2.5, 201.6.2, 201.7.9.2.9, 201.8.1, 201.8.2.1 and 201.8.4.2 as well as the required application of risk and usability management 4.2, 201.7.1.1, 201.12.2.
	Any restrictions on use must be indicated on the label or in the instructions for use.	Covered by 201.7.9.2, 201.7.9.2.2 and 201.7.9.3.1.
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:	
	– the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	There are no risks of injury, in connection with the physical features, including the volume/pressure ratio, dimensional and ergonomic features of HEARING INSTRUMENTS. Mechanical risks are covered by 201.9.

No.	Essential Requirements	Coverage of EN 60601-2-66
	– risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration;	The reference to EN 60118-13 in 201.17 of this document provides design and test requirements with regards to magnetic fields, external electrical influences, electrostatic discharges which are suitable to remove or minimize as far as possible risks to hearing aids. 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 risks to hearing aids from pressure, temperature or variations in pressure.
	– the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	The reference to EN 60118-13 in 201.17 of this document provides design requirements to remove or minimize as far as possible risks connected with reciprocal interference by EMC phenomena with other devices. 201.7.9.2.2 contains requirements for warnings regarding other potential causes of reciprocal interference.
	– risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	HEARING INSTRUMENTS do not need calibration. Maintenance is possible. 201.15.2 contains requirements with regards to serviceability.
9.3	Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition.	Risks of fire and high temperatures covered in 201.11.1.1, 201.13.1.2 The requirements for HEARING INSTRUMENTS that are intended to be used in explosive and oxygen-enriched atmospheres are not covered in this document.
	Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	HEARING INSTRUMENTS are normally not exposed to flammable substances or to substances which could cause combustion. The requirements for HEARING INSTRUMENTS that are intended to be used in explosive and oxygen-enriched atmospheres are not covered in this document.

No.	Essential Requirements	Coverage of EN 60601-2-66
10	**Devices with a measuring function**	
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device.	Not applicable to HEARING INSTRUMENTS.
	The limits of accuracy must be indicated by the manufacturer.	Not applicable to HEARING INSTRUMENTS.
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	Not applicable to HEARING INSTRUMENTS.
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.	Not applicable to HEARING INSTRUMENTS.
11	**Protection against radiation**	General Guidance note 2 and 3 shall be observed
11.1	General	
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Not applicable to HEARING INSTRUMENTS.
11.2	Intended radiation	
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	Not applicable to HEARING INSTRUMENTS.
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	Not applicable to HEARING INSTRUMENTS.
11.3	Unintended radiation	
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	Covered with respect to electromagnetic compatibility in 201.17 by the requirement to apply EN 60118-13 as well as applicable radio standards for wireless interfaces. The risks of tissue exposure to the emission of electromagnetic fields by wireless interfaces of HEARING INSTRUMENTS are not covered in this document.

No.	Essential Requirements	Coverage of EN 60601-2-66
11.4	Instructions	
11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Not applicable to HEARING INSTRUMENTS.
11.5	Ionizing radiation	
11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	Not applicable to HEARING INSTRUMENTS.
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	Not applicable to HEARING INSTRUMENTS.
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	Not applicable to HEARING INSTRUMENTS.
12	**Requirements for medical devices connected to or equipped with an energy source**	General Guidance note 2 and 3 shall be observed
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system), appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	Covered by 201.14.
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.	Covered in respect of devices which incorporate SW by 201.14.
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	Not applicable to HEARING INSTRUMENTS.
12.3	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	Not applicable to HEARING INSTRUMENTS.
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient’s state of health.	Not applicable to HEARING INSTRUMENTS.

No.	Essential Requirements	Coverage of EN 60601-2-66
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	Covered by reference to EN 60118-13 in 201.17 of this document with respect to risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.
12.6	Protection against electrical risks	
12.6.1	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices be installed correctly.	Electrical risks covered in 201.8 for normal conditions and 201.13 in fault conditions.
12.7	Protection against mechanical and thermal risks	
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	HEARING INSTRUMENTS are not creating a risk from vibration.
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	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	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	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 INSTRUMENTS.
12.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	Covered by 201.11.1 Excessive temperatures
12.8	Protection against the risks posed to the patient by energy supplies or substances	
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	Not applicable to HEARING INSTRUMENTS; no supply of energy or substances to the patient.

No.	Essential Requirements	Coverage of EN 60601-2-66
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.	Not applicable to HEARING INSTRUMENTS.
	Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	The reduction of unintentional exposure to excessive acoustic noise is covered in 201.9.6
12.9	The function of the controls and indicators must be clearly specified on the devices	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.
	Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	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	**Information supplied by the manufacturer**	
13.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use.	Covered in respect of the following: 201.7.9.2 Instructions for use. 201.7.9.2.16 Technical description.
	As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.	Covered in respect of information on the device in 201.7.2.2. 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.
	Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	Requirements for instruction for use covered in 201.7.9.2.
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	Requirement to use symbols covered by reference to the general standard 7.6 and Annex D. 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.

No.	Essential Requirements	Coverage of EN 60601-2-66
13.3	The label must bear the following particulars: (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the Community; (b) the details strictly necessary to identify the device and the contents of the packaging especially for the users; (c) where appropriate, the word 'STERILE'; (d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number; (e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; (f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; (g) if the device is custom-made, the words 'custom-made device'; (h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'; (i) any special storage and/or handling conditions; (j) any special operating instructions; (k) any warnings and/or precautions to take; (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number; (m) where applicable, method of sterilization;	Covered in respect of the following, in part by reference to the general standard: a) 201.7.2.2 and 201.7.9.1 Identification (partially covered: in order to comply with this ER, name and address must be used). Specifics of imported devices (authorized representative) not covered. b) 201.7.9.1 Identification (limited to details related to the identification of the device) c) Not applicable to HEARING INSTRUMENTS. d) Serial number required in 201.7.2.2. e), f) Not applicable to HEARING INSTRUMENTS. g) Not covered h) Not covered i) 201.7.2.17 Protective packaging. j) 201.7.2 Marking on the outside of equipment and parts. 7.3 Marking on the inside of equipment and parts. 7.5 Safety signs k) Covered in 201.7.9.2.2, 201.7.9.2.4, 201.7.9.2.5 and 201.9.6. l) 201.7.2.2 Identification m) Not applicable to HEARING INSTRUMENTS.
	(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	Not applicable to HEARING INSTRUMENTS.
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	Covered in 201.7.9.2.1
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Serial number required in 201.7.2.2.

No.	Essential Requirements	Coverage of EN 60601-2-66
13.6	Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; (e) where appropriate, information to avoid certain risks in connection with implantation of the device; (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilization;	a) Details referred to in section 13.3 with the exception of (d) and (e) covered by 201.7.9 and the clauses as shown in section 13.3 above. b) Performances referred to in Section 3 covered in 201.7.9.3. c) Not applicable to HEARING INSTRUMENTS. d) Covered in 201.7.9.2.12 and 201.7.9.2.1. e) Not applicable to HEARING INSTRUMENTS in the scope of this document. f) Not applicable to HEARING INSTRUMENTS. g) Not applicable to HEARING INSTRUMENTS.
	(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I; If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; (i) details of any further treatment or handling needed before the device can be used (for example sterilization, final assembly, etc.); (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	h), i) j) Not applicable to HEARING INSTRUMENTS.

No.	Essential Requirements	Coverage of EN 60601-2-66
	The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: (k) precautions to be taken in the event of changes in the performance of the device; (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; (n) precautions to be taken against any special, unusual risks related to the disposal of the device; (o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; (p) degree of accuracy claimed for devices with a measuring function; (q) date of issue or the latest revision of the instructions for use.	k), l) covered in 201.7.9.2.1 m), n), o), p) Not applicable to HEARING INSTRUMENTS. q) Not covered.

IEC 60601-2-66

Edition 2.0 2015-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.180.15; 17.140.50

ISBN 978-2-8322-2766-4

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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

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

This second edition cancels and replaces the first edition published in 2012. It constitutes a technical revision to adapt IEC 60601-2-66:2012 to the technical corrections introduced by Amendment 1 (2012) to IEC 60601-1:2005, as well as to clarify and correct the wording of this particular standard and to implement minor changes requested by interested parties.

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

FDIS	Report on voting
29/851/FDIS	29/869/RVD

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

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

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.

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

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

INTRODUCTION

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+A1:2012, *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:

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

IEC 60950-1:2005/AMD1:2009

IEC 60950-1:2005/AMD2:2013

Addition:

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

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

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

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

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

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