Irish Standard
I.S. EN 60601-2-66:2015

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

I.S. EN 60601-2-66:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

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This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

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National Foreword

I.S. EN 60601-2-66:2015 is the adopted Irish version of the European Document EN 60601-2-66:2015, Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

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

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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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

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Ref. No. EN 60601-2-66:2015 E

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

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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 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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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*

201.3 Terms and definitions

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

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