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Elektrilised meditsiiniseadmed. Osa 2-66: Erinõuded kuuldeseadmete ja kuuldeseadmesüsteemide esmasele ohutusele ja olulistele toimimisnäitajatele

Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems (IEC 60601-2-66:2012)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-2-66:2013 sisaldab Euroopa standardi EN 60601-2-66:2013 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-66:2013 consists of the English text of the European standard EN 60601-2-66:2013.
Standard on kinnitatud Eesti Standardikeskuse 31.01.2013 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.01.2013 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 18.01.2013.	Date of Availability of the European standard text 18.01.2013.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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ICS 11.180.15, 17.140.50

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-66

January 2013

ICS 11.180.15; 17.140.50

English version

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

(IEC 60601-2-66:2012)

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

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

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CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

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

Foreword

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

The following dates are fixed:

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

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

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.),
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

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

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

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

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

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

Endorsement notice

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

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

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

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

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

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

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

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

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Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

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

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

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

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

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CONTENTS

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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.

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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

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201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY of HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS, hereafter also referred to as ME EQUIPMENT or ME SYSTEM.

If a clause or subclause is specifically intended to be applicable to HEARING INSTRUMENTS only, or to HEARING INSTRUMENT SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to HEARING INSTRUMENTS and to HEARING INSTRUMENT SYSTEMS, as relevant.

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

NOTE See also 201.4.2. (RISK MANAGEMENT).

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

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

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

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

This standard does not apply to:

– cochlear implants or other implanted HEARING INSTRUMENTS;

– bone conduction HEARING INSTRUMENTS;

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

– educational HEARING INSTRUMENTS (i.e. group HEARING INSTRUMENTS, auditory trainers etc.);
– the application of a HEARING INSTRUMENT for the measurement of hearing levels. IEC 60645-1 applies;
– audio-frequency induction-loop systems or their component parts, as described in IEC 60118-4 and IEC 62489-1;
– assisted HEARING INSTRUMENT SYSTEMS using infra-red or radio;
– the sound generating function of a tinnitus masker.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY requirements for HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS as defined in 201.3.202 and 201.3.203.

201.1.3 * Collateral standards

Addition:

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

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

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

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"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

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

201.2 Normative references

Clause 2 of the general standard applies except as follows:

Replacement of the introductory paragraph:

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

NOTE Informative references are listed in the bibliography.

Replacement:

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

Addition:

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

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

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

IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

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

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

201.3 Terms and definitions

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

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

201.3.73
OPERATOR

Addition:

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

201.3.76
PATIENT

Addition:

Note 1 to entry: In this particular standard and in applying the requirements of the general standard, the term PATIENT has the meaning explained in the second paragraph of 4.1 of the general standard. The PATIENT is also usually the OPERATOR.

The term PATIENT is being used in this standard in line with the general terminology in the medical product field. It is however understood, that the user of a HEARING INSTRUMENT is typically not an ill person but someone healthy with a hearing impairment in a HOME HEALTHCARE ENVIRONMENT.

201.3.113
SERVICE PERSONNEL

Replacement:

individuals or entity that assemble, maintain or repair HEARING INSTRUMENTS or HEARING INSTRUMENT SYSTEMS

201.3.132
TYPE B APPLIED PART

Replacement:

APPLIED PART complying with the specified requirements of this particular standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT

Addition:

201.3.201
HEARING HEALTH-CARE PROFESSIONAL
acoustician, audiologist and trained clinical staff

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

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