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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-66:2015 sisaldab Euroopa standardi EN 60601-2-66:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-66:2015 consists of the English text of the European standard EN 60601-2-66:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 27.11.2015.	Date of Availability of the European standard is 27.11.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.180.15, 17.140.50

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)

This European Standard was approved by CENELEC on 2015-07-31. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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

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

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

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).

CONTENTS

FOREWORD 3
INTRODUCTION 5
201.1 Scope, object and related standards 6
201.2 Normative references 8
201.3 Terms and definitions 8
201.4 General requirements 10
201.5 General requirements for testing ME EQUIPMENT 10
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 12
201.7 ME EQUIPMENT identification, marking and documents 13
201.8 *Protection against electrical HAZARDS from ME EQUIPMENT 18
201.9 *Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 21
201.10 Protection against unwanted and excessive radiation HAZARDS 23
201.11 *Protection against excessive temperatures and other HAZARDS 23
201.12 *Accuracy of controls and instruments and protection against hazardous outputs 24
201.13 *HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 25
201.14 *PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 28
201.15 *Construction of ME EQUIPMENT 29
201.16 *ME SYSTEMS 31
201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 31
Annexes 32
Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of THE PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT 32
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures 32
Annex H (informative) PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation 32
Annex I (informative) ME SYSTEMS aspects 32
Annex J (informative) Survey of insulation paths 32
Annex K (informative) Simplified PATIENT LEAKAGE CURRENT diagrams 33
Annex L (normative) Insulated winding wires for use without interleaved insulation 33
Annex AA (informative) Particular guidance and rationale 34
Annex BB (informative) Abbreviations 39
Bibliography 40
Index of defined terms used in this particular standard 41

Figure 201.101 – Measuring circuit for LEAKAGE CURRENT 20

Table 201.102 – MECHANICAL HAZARDS to be considered 21
Table AA.101 – Summary of the approach of this standard 35

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;

---

[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.