IEC 60601-2-66

Edition 3.0 2019-10
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

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

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CONTENTS

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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

This third edition cancels and replaces the second edition published in 2015. It constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) revision of the definition about ESSENTIAL PERFORMANCE;
b) revision of the application of IEC 60601-1-2:2014 for electromagnetic disturbances*;*
c) correction of the used voltage for HEARING AIDS from 1,6 V to 4,5 V;
d) correction of the drop test level from 1,5 m to 1,0 m;
e) correction of the wording of IEC 60601-2-66:2015.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
29/1023/FDIS	29/1030/RVD

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

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

In this document, the following print types are used:

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

In referring to the structure of this document, the term

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

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

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

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

In 1998, the HEARING ~~INSTRUMENT~~ AID industry represented by the European hearing instrument manufacturers association (EHIMA) attempted to establish a standard with the main purpose of providing MANUFACTURERS with a guide to demonstrate conformity with the European Medical Devices Directive 93/42/EEC.

The draft document prEN 50220 failed CENELEC vote and was published as "EHIMA standard" in June 1998 with almost identical content. EHIMA concluded in 2009 that the requirements of that standard were no longer up to date and an internationally accepted standard for HEARING ~~INSTRUMENT~~ AID 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.~~

This particular standard amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, hereinafter referred to as the "general standard".

A general guidance and rationale for the requirements of this particular standard are given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this document.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY of HEARING ~~INSTRUMENTS~~ AIDS and HEARING ~~INSTRUMENT~~ AID SYSTEMS, hereafter also referred to as ME EQUIPMENT or ME SYSTEM.

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

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

NOTE See also ~~201.4.2. (RISK MANAGEMENT)~~ 4.2 of the general standard.

ACCESSORIES to HEARING ~~INSTRUMENTS~~ AIDS in the HOME HEALTHCARE ENVIRONMENT (e.g. remote control units, audio streamers, battery chargers, power supplies) ~~are covered by the most~~ can be tested according to the applicable standard, IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards. Alternatively, the general standard may be applied. HEARING ~~INSTRUMENTS~~ AIDS do not have a MAINS PART intended for connection to AC SUPPLY MAINS. The connection to the SUPPLY MAINS of a HEARING ~~INSTRUMENT~~ AID 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.~~

ACCESSORIES with FUNCTIONAL CONNECTION to a HEARING AID may form a HEARING AID SYSTEM. HEARING AID related ACCESSORIES that are not physically connected to the HEARING AID during NORMAL USE are not considered to be APPLIED PART, because they do not directly contribute to the INTENDED USE of the HEARING AID.

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

Wireless programming interfaces are covered by the applicable standard IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards. Alternatively, the general standard may be applied.

Programming interfaces with wired connection to the HEARING AID are covered by the general standard.

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

This document does not apply to:

– cochlear implants or other implanted HEARING ~~INSTRUMENTS~~ AIDS;

– bone conduction HEARING ~~INSTRUMENTS~~AIDS;

– educational HEARING ~~INSTRUMENTS~~AIDS (i.e. group HEARING ~~INSTRUMENTS~~AIDS, auditory trainers etc.);

– the application of a HEARING ~~INSTRUMENT~~AID for the measurement of hearing levels~~.~~; IEC 60645-1 applies;

– fix installed audio-frequency induction-loop systems or their component parts, as described in IEC 60118-4 and IEC 62489-1;

~~– assisted HEARING INSTRUMENT SYSTEMS using infra-red or radio;~~

– the sound generating function of a tinnitus masker.

This document does not address applicable testing for intentional RF radiation of wireless equipment (e.g. maximum radiated output power, modulation bandwidth, etc.).

201.1.2 Object

Replacement:

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

201.1.3 * Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

~~IEC 60601-1-2,~~ IEC 60601-1-3, IEC 60601-1-9 and 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 and IEC 60601-1:2005/AMD1:2012 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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

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

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

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

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through ~~3.139~~ 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

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

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*
IEC 60950-1:2005/AMD1:2009
IEC 60950-1:2005/AMD2:2013

Addition:

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

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

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

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

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

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

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

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 and the following apply~~, except as follows~~.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 56.

201.3.73
OPERATOR
Addition:

Note 101 to entry Usually equals to PATIENT for HEARING ~~instruments~~ AIDS in a home healthcare environment.

201.3.76
PATIENT

~~*Addition*~~

Replacement:

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 document in line with the general terminology in the medical product field. It is, however, understood that the user of a HEARING ~~INSTRUMENT~~ AIDS 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~~ AIDS or HEARING ~~INSTRUMENT~~ AID 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~~

HEARING AID PROFESSIONAL
audiologically competent person who professionally assesses hearing, selects, fits and delivers HEARING AID systems and rehabilitation services to persons with hearing impairment

201.3.202
~~**HEARING INSTRUMENT**~~
HEARING AID
ME EQUIPMENT which picks up sound and delivers processed sound to the ear canal through air-conduction

Note 1 to entry: A HEARING ~~INSTRUMENT~~ AID includes all detachable parts that are essential for the performance of its INTENDED USE.

201.3.203
HEARING SYSTEM
HEARING ~~INSTRUMENT~~ AID SYSTEM
combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is a HEARING ~~INSTRUMENT~~ AID to be inter-connected by specified FUNCTIONAL CONNECTIONS

201.3.204
SOUND PRESSURE LEVEL
SPL
L_p
ten times the logarithm to the base 10 of the ratio of the root-mean-square of the sound pressure in the time domain, p, to the square of ~~a~~ the reference value, p_0, expressed in decibels

$$L_p = 10 \lg \frac{p^2}{p_0^2} \text{ dB}$$

where the reference value, p_0, is 20 μPa

Note 1 to entry: ~~Because of practical limitations of the measuring instruments,~~ p^2 is ~~always~~ understood to denote the square of a frequency-weighted, frequency-band-limited or time-weighted sound pressure.

If specific frequency and time weightings as specified in IEC 61672-1 and/or specific frequency bands are applied, this should be indicated by appropriate subscripts; e.g. $L_{p,AF}$ denotes the A-weighted SOUND PRESSURE LEVEL with time weighting F.