IEC 60601-2-66

Edition 3.0 2019-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 2-66: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de correction auditive et des systèmes de correction auditive

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

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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 aids and hearing 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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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.

INTRODUCTION

In 1998, the HEARING 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 AID safety published by IEC or ISO to demonstrate compliance with regulatory requirements should be produced.

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 aids and hearing 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 AIDS and HEARING 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 AIDS only, or to HEARING 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 AIDS and to HEARING AID SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of HEARING AIDS or HEARING 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 4.2 of the general standard.

ACCESSORIES to HEARING AIDS in the HOME HEALTHCARE ENVIRONMENT (e.g. remote control units, audio streamers, battery chargers, power supplies) 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 AIDS do not have a MAINS PART intended for connection to AC SUPPLY MAINS. The connection to the SUPPLY MAINS of a HEARING AID SYSTEM is covered by power supply, charger or other types of ACCESSORIES.

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.

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 AIDS, even if supplied separately (e.g. ear hooks, domes, wax guards etc.), are not considered as ACCESSORIES, but as component parts.

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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.*