

# 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**



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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

The text of this particular standard is based on the following documents:

FDIS	Report on voting
29/777/FDIS	29/792/RVD

Full information on the voting for the approval of this particular 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.

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- “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.

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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.

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- 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- withdrawn,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.

Withdrawn