

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**



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CONTENTS

FOREWORD	4
INTRODUCTION	7
201.1 Scope, object and related standards	8
201.2 Normative references	10
201.3 Terms and definitions	11
201.4 General requirements	12
201.5 General requirements for testing ME EQUIPMENT	13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	15
201.7 ME EQUIPMENT identification, marking and documents	15
201.8 * Protection against electrical HAZARDS from ME EQUIPMENT	21
201.9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	23
201.10 * Protection against unwanted and excessive radiation HAZARDS	25
201.11 * Protection against excessive temperatures and other HAZARDS	25
201.12 * Accuracy of controls and instruments and protection against hazardous outputs	27
201.13 * HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	28
201.14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	30
201.15 * Construction of ME EQUIPMENT	31
201.16 * ME SYSTEMS	33
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	33
Annexes	35
Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT	36
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures	37
Annex H (informative) PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation	38
Annex I (informative) ME SYSTEMS aspects	39
Annex J (informative) Survey of insulation paths	40
Annex K (informative) Simplified PATIENT LEAKAGE CURRENT diagrams	41
Annex L (normative) Insulated winding wires for use without interleaved insulation	42
Annex AA (informative) Particular guidance and rationale	43
Annex BB (informative) Abbreviations	48
Annex CC (informative) Essential performance	49
Annex DD (informative) Electromagnetic compatibility of ME EQUIPMENT	50
Bibliography	52
Index of defined terms used in this particular standard	54
Figure 201.101 – Measuring circuit for LEAKAGE CURRENT (see 201.8.7.4.7)	22
Table 201.101 – MECHANICAL HAZARDS to be considered	24
Table AA.101 – Summary of the approach of this document	44

Table DD.101 – Example of applicable standards for HEARING AID specific setting for
RF radiated emissions 50

Table DD.102 – Example of applicable tests 51

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems**

FOREWORD

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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:

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- "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.