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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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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 ~~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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
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.

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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;

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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.

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.

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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.

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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

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.*

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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.

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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

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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*

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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

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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.

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– 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).

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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.

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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.

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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

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.

---

[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.*

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This document does not apply to:

– cochlear implants or other implanted HEARING AIDS;
– bone conduction HEARING AIDS;
– educational HEARING AIDS (i.e. group HEARING AIDS, auditory trainers etc.);
– the application of a HEARING 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;
– 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 AIDS and HEARING 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 60601-1-3, IEC 60601-1-9 and IEC 60601-1-10 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.

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"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 3.147, 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 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*

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

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SOMMAIRE

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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

AVANT-PROPOS

1) La Commission Electrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
2) Les décisions ou accords officiels de l'IEC concernant les questions techniques représentent, dans la mesure du possible, un accord international sur les sujets étudiés, étant donné que les Comités nationaux de l'IEC intéressés sont représentés dans chaque comité d'études.
3) Les Publications de l'IEC se présentent sous la forme de recommandations internationales et sont agréées comme telles par les Comités nationaux de l'IEC. Tous les efforts raisonnables sont entrepris afin que l'IEC s'assure de l'exactitude du contenu technique de ses publications; l'IEC ne peut pas être tenue responsable de l'éventuelle mauvaise utilisation ou interprétation qui en est faite par un quelconque utilisateur final.
4) Dans le but d'encourager l'uniformité internationale, les Comités nationaux de l'IEC s'engagent, dans toute la mesure possible, à appliquer de façon transparente les Publications de l'IEC dans leurs publications nationales et régionales. Toutes divergences entre toutes Publications de l'IEC et toutes publications nationales ou régionales correspondantes doivent être indiquées en termes clairs dans ces dernières.
5) L'IEC elle-même ne fournit aucune attestation de conformité. Des organismes de certification indépendants fournissent des services d'évaluation de conformité et, dans certains secteurs, accèdent aux marques de conformité de l'IEC. L'IEC n'est responsable d'aucun des services effectués par les organismes de certification indépendants.
6) Tous les utilisateurs doivent s'assurer qu'ils sont en possession de la dernière édition de cette publication.
7) Aucune responsabilité ne doit être imputée à l'IEC, à ses administrateurs, employés, auxiliaires ou mandataires, y compris ses experts particuliers et les membres de ses comités d'études et des Comités nationaux de l'IEC, pour tout préjudice causé en cas de dommages corporels et matériels, ou de tout autre dommage de quelque nature que ce soit, directe ou indirecte, ou pour supporter les coûts (y compris les frais de justice) et les dépenses découlant de la publication ou de l'utilisation de cette Publication de l'IEC ou de toute autre Publication de l'IEC, ou au crédit qui lui est accordé.
8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

La Norme internationale IEC 60601-2-66 a été établie par le comité d'études 29 de l'IEC: Électroacoustique.

Cette troisième édition annule et remplace la deuxième édition parue en 2015. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) révision de la définition des PERFORMANCES ESSENTIELLES;
b) révision de l'application de l'IEC 60601-1-2:2014 pour les perturbations électromagnétiques;

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c) correction de la tension utilisée pour les APPAREILS DE CORRECTION AUDITIVE de 1,6 V à 4,5 V;

d) correction du niveau d'essai de chute de 1,5 m à 1,0 m;

e) correction de la formulation de l'IEC 60601-2-66:2015.

Le texte de cette Norme internationale est issu des documents suivants:

FDIS	Rapport de vote
29/1023/FDIS	29/1030/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;

– *modalités d'essais: caractères italiques;*

– indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères romains. Le texte normatif à l'intérieur des tableaux est également en petits caractères;

– TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DANS LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme:

– "article" désigne l'une des dix-sept divisions numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);

– "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans la présente norme particulière, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif". Ainsi un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité au présent document;

– "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée, mais n'est pas obligatoire pour la conformité au présent document;

– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, ou au début d'un alinéa ou d'un titre de tableau, il indique l'existence d'un guide ou d'une justification applicable à cet élément à consulter à l'Annexe AA.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

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Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

NOTE L'attention des utilisateurs du présent document est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

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INTRODUCTION

En 1998, l'industrie des APPAREILS DE CORRECTION AUDITIVE représentée par l'Association européenne des fabricants d'instruments d'audition (EHIMA) a tenté d'établir une norme, avec pour objectif principal de fournir aux FABRICANTS un guide montrant la conformité à la Directive européenne 93/42/CEE Dispositifs médicaux.

Le résultat du vote CENELEC concernant ce projet de norme européenne prEN 50220 a été négatif et le document a été publié en tant que "norme EHIMA" en juin 1998 avec un contenu presque identique. L'EHIMA a conclu en 2009 que les exigences de cette norme n'étaient plus d'actualité et qu'il convenait de produire une norme acceptée au niveau international pour la sécurité des APPAREILS DE CORRECTION AUDITIVE, publiée par l'IEC ou l'ISO, pour démontrer la conformité aux exigences réglementaires.

La présente norme particulière modifie et complète l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, désignée ci-après par "norme générale".

Une recommandation générale et une justification relatives aux exigences de la présente norme particulière sont indiquées à l'Annexe AA. Il est considéré que la connaissance des raisons qui ont conduit à énoncer ces exigences non seulement facilite l'application correcte de la présente norme particulière, mais accélérera en son temps toute révision rendue nécessaire du fait de modifications dans la pratique clinique ou d'évolutions technologiques. Cependant, l'Annexe AA ne fait pas partie des exigences du présent document.

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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

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale[1] s'applique, avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE des APPAREILS DE CORRECTION AUDITIVE et des SYSTEMES DE CORRECTION AUDITIVE, également appelés ci-après "APPAREILS EM" ou "SYSTEMES EM".

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS DE CORRECTION AUDITIVE, ou uniquement aux SYSTEMES DE CORRECTION AUDITIVE, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si ce n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS DE CORRECTION AUDITIVE et aux SYSTEMES DE CORRECTION AUDITIVE, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue des APPAREILS DE CORRECTION AUDITIVE ou des SYSTEMES DE CORRECTION AUDITIVE dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document, à l'exception de 201.7.9.2 et de 201.9.6.

NOTE Voir aussi 4.2 de la norme générale.

Les ACCESSOIRES des APPAREILS DE CORRECTION AUDITIVE dans l'ENVIRONNEMENT DE SOINS A DOMICILE (par exemple, unités de commande à distance, diffuseurs de flux audio, chargeurs de batteries, alimentations) peuvent être soumis aux essais selon la norme applicable IEC 60065, IEC 60950-1, IEC 62368-1 ou d'autres normes de sécurité IEC applicables. En variante, il est admis d'appliquer la norme générale. Les APPAREILS DE CORRECTION AUDITIVE n'ont pas de PARTIE RELIEE AU RESEAU destinée à être connectée au RÉSEAU D'ALIMENTATION à courant alternatif. La connexion au RESEAU D'ALIMENTATION d'un SYSTEME DE CORRECTION AUDITIVE est couverte par l'alimentation, le chargeur ou d'autres types d'ACCESSOIRES.

Les ACCESSOIRES à CONNEXION FONCTIONNELLE à un APPAREIL DE CORRECTION AUDITIVE peuvent former un SYSTEME D'APPAREIL DE CORRECTION AUDITIVE. Les ACCESSOIRES de l'APPAREIL DE CORRECTION AUDITIVE qui ne sont pas physiquement reliés à l'APPAREIL DE CORRECTION AUDITIVE en UTILISATION NORMALE ne sont pas considérés comme PARTIE APPLIQUEE, puisqu'ils ne participent pas directement à l'UTILISATION PREVUE de l'APPAREIL DE CORRECTION AUDITIVE.

Les interfaces de programmation sans fil sont couvertes par la norme applicable IEC 60065, IEC 60950-1, IEC 62368-1 ou d'autres normes de sécurité IEC applicables. En variante, il est admis d'appliquer la norme générale.

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[1] La norme générale est l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles.*

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Les interfaces de programmation à connexion câblée à l'APPAREIL DE CORRECTION AUDITIVE sont couvertes par la norme générale.

NOTE Les parties amovibles des APPAREILS DE CORRECTION AUDITIVE, même si elles sont fournies séparément (par exemple, contours d'oreille, dômes, filtres anticérumen, etc.), ne sont pas considérées comme des ACCESSOIRES, mais comme des composants.

Le présent document ne s'applique pas:

– aux implants cochléaires ou autres APPAREILS DE CORRECTION AUDITIVE implantés;
– aux APPAREILS DE CORRECTION AUDITIVE à conduction osseuse;
– aux APPAREILS DE CORRECTION AUDITIVE de formation (c'est-à-dire les APPAREILS DE CORRECTION AUDITIVE de groupe, les dispositifs d'entraînement auditif, etc.);
– à l'application d'un APPAREIL DE CORRECTION AUDITIVE au mesurage des niveaux d'audition; l'IEC 60645-1 s'applique;
– aux systèmes fixes de boucles d'induction audiofréquences ou à leurs composants, tels que décrits dans l'IEC 60118-4 et l'IEC 62489-1;
– à la fonction de génération acoustique d'un masqueur d'acouphène.

Le présent document ne traite pas des essais applicables aux rayonnements RF volontaires des appareils sans fil (par exemple, puissance de sortie rayonnée maximale, largeur de bande de modulation, etc.).

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir des exigences particulières pour la SECURITE DE BASE des APPAREILS DE CORRECTION AUDITIVE et des SYSTEMES DE CORRECTION AUDITIVE tels qu'ils sont définis en 201.3.202 et en 201.3.203.

201.1.3 * Normes collatérales

Addition:

La présente norme particulière fait référence aux normes collatérales applicables énumérées à l'Article 2 de la norme générale et à l'Article 201.2 de la présente norme particulière.

L'IEC 60601-1-3, l'IEC 60601-1-9 et l'IEC 60601-1-10 ne s'appliquent pas. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles que publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales, en fonction de ce qui est approprié pour l'APPAREIL EM particulier à l'étude, et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, dans la présente norme particulière, le terme “norme générale” désigne l'IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012. Les normes collatérales sont désignées par leur numéro de document.

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La numérotation des articles et des paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe "201" (par exemple, 201.1 dans le présent document aborde le contenu de l'Article 1 de la norme générale) ou à celle de la norme collatérale applicable avec le préfixe "20x", où x est le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple, 202.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale sont précisées en utilisant les termes suivants:

"Remplacement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

"Addition" signifie que le texte de la présente norme particulière vient s'ajouter aux exigences de la norme générale ou de la norme collatérale applicable.

"Amendement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué dans le texte de la présente norme particulière.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans la norme générale sont numérotées de 3.1 à 3.147, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes supplémentaires sont appelées AA, BB, etc., et les points supplémentaires aa), bb), etc.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à la norme générale, à toutes les normes collatérales applicables et à la présente norme particulière considérées ensemble.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, bien que potentiellement non pertinent, s'applique sans modification; lorsqu'il est prévu qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que pertinente, ne s'applique pas, cela est expressément mentionné dans la présente norme particulière.

201.2 Références normatives

NOTE Une liste de références informatives est donnée dans la Bibliographie.

L'Article 2 de la norme générale s'applique, avec les exceptions suivantes:

Remplacement:

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

IEC 60950-1:2005, *Matériels de traitement de l'information – Sécurité – Partie 1: Exigences générales*
IEC 60950-1:2005/AMD1:2009
IEC 60950-1:2005/AMD2:2013

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Addition:

IEC 60118-0:2015, *Électroacoustique – Appareils de correction auditive – Partie 0: Mesure des caractéristiques fonctionnelles des appareils de correction auditive*

IEC 60118-13, *Électroacoustique – Appareils de correction auditive – Partie 13: Compatibilité électromagnétique (CEM)*

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles.*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-11:2015, *Appareils électromédicaux – Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles – Norme Collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile*

IEC 62368-1:2018, *Équipements des technologies de l'audio/vidéo, de l'information et de la communication – Partie 1: Exigences de sécurité*