IEC 60601-2-66

Edition 2.0 2015-06

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

IEC 60601-2-66:2015-06(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 instruments and hearing instrument systems

FOREWORD

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

This second edition cancels and replaces the first edition published in 2012. It constitutes a technical revision to adapt IEC 60601-2-66:2012 to the technical corrections introduced by Amendment 1 (2012) to IEC 60601-1:2005, as well as to clarify and correct the wording of this particular standard and to implement minor changes requested by interested parties.

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

FDIS	Report on voting
29/851/FDIS	29/869/RVD

Full information on the voting for the approval of this 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.

In referring to the structure of this standard, 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 standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

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

– "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 publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- 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.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument 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 International Standard applies to the BASIC SAFETY of HEARING INSTRUMENTS and HEARING INSTRUMENT 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 only, or to HEARING INSTRUMENT 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 and to HEARING INSTRUMENT SYSTEMS, as relevant.

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

NOTE See also 201.4.2. (RISK MANAGEMENT).

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

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

This standard does not apply to:

– cochlear implants or other implanted HEARING INSTRUMENTS;

– bone conduction HEARING INSTRUMENTS;

[1] The general standard is IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

– educational HEARING INSTRUMENTS (i.e. group HEARING INSTRUMENTS, auditory trainers etc.);
– the application of a HEARING INSTRUMENT for the measurement of hearing levels. IEC 60645-1 applies;
– 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.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY requirements for HEARING INSTRUMENTS and HEARING INSTRUMENT 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.

IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-9, 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 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 standard 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, additional definitions in this standard 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 standard" 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

Clause 2 of the general standard applies except as follows:

Replacement:

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 characteristics*

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*

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 apply, except as follows:

NOTE An index of defined terms is found beginning on page 41.

201.3.73
OPERATOR

Addition:

Note 1 to entry: Usually equal to patient for hearing instruments in a home healthcare environment.

201.3.76
PATIENT

Addition:

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

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 includes all detachable parts that are essential for the performance of its intended use.

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

201.3.204
SOUND PRESSURE LEVEL
SPL
L_p
ten times the logarithm to the base 10 of the ratio of the square of the sound pressure, p, to the square of a 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.

Note 2 to entry: This definition is technically in accordance with ISO 80000-8:2007, 8-22.

Note 3 to entry: The note to entry concerning the origin of the English abbreviation "SPL" concerns the French text only.

[SOURCE: ISO/TR 25417:2007, 2.2]

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Replacement:

Unless otherwise specified, the requirements of this standard shall apply in NORMAL USE and reasonably foreseeable misuse.

When applying this standard to HEARING INSTRUMENTS or HEARING INSTRUMENT SYSTEMS, the definitions and requirements that use the term PATIENT shall be considered as applying to the person for whom the HEARING INSTRUMENT or HEARING INSTRUMENT SYSTEMS is intended.

201.4.3 * Essential performance

Replacement:

HEARING INSTRUMENTS do not have an ESSENTIAL PERFORMANCE.

201.4.6 ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Subclause 4.6 of the general standard does not apply.

201.4.10 Power supply

Subclause 4.10 of the general standard does not apply.

201.4.11 Power input

Subclause 4.11 of the general standard does not apply.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.2 Number of samples

Replacement:

TYPE TESTS are performed on a representative sample of the item being tested. If multiple products are under consideration, which have a similar mechanical and electrical architecture, then an engineering analysis by the MANUFACTURER may justify a single representative sample for a family of products.

201.5.3 Ambient temperature, humidity, atmospheric pressure

Replacement:

After the HEARING INSTRUMENT or HEARING INSTRUMENT SYSTEM to be tested has been set up for NORMAL USE, tests are performed within the range of environmental conditions indicated in the technical description, as specified by the MANUFACTURER.

201.5.4 Other conditions

Addition:

aa) Inventory stocking conditions are specified by the MANUFACTURER.

bb) HEARING INSTRUMENT transport conditions are specified by the MANUFACTURER.

201.5.5 Supply voltages, type of current, nature of supply, frequency

Replacement:

a) Where test results are influenced by deviations of the supply voltage from its rated value, the effect of such deviations shall be taken into account.

b) HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS designed for more than one rated voltage shall be tested in conditions related to the least favourable voltage and nature of supply.

c) HEARING INSTRUMENTS for which alternative ACCESSORIES or detachable parts can be connected as specified in the ACCOMPANYING DOCUMENTS shall be tested with those ACCESSORIES or detachable parts that result in the least favourable conditions.

d) If the instructions for use specify that a HEARING INSTRUMENT or a HEARING INSTRUMENT SYSTEM is intended to receive its power from a separate power supply, it shall be connected to such a power supply.

201.5.7 Humidity preconditioning treatment

Replacement:

Where climatic conditions could influence the safety of a HEARING INSTRUMENT or HEARING INSTRUMENT SYSTEM or its parts, it shall be subjected to a humidity preconditioning treatment prior to the tests of 201.8.7.4.

HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS or theirs parts shall be set up completely (or where necessary partially). Covers used during transport and storage shall be detached.

Parts that can be detached without the use of tools shall be detached, but tested simultaneously with the major part.

ACCESS COVERS that can be opened or detached without the use of tools shall be opened and detached.

The humidity preconditioning treatment shall be performed in a humidity cabinet containing air with a relative humidity of 93 % ± 3 % where the ME EQUIPMENT or its parts under test are located. The humidity conditions at other locations in the chamber may vary by ± 6 %. The temperature of the air in the cabinet, at all places where HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS can be located, shall be maintained within 2 °C of any convenient value *T* in the range of + 20 °C to + 30 °C. Before being placed in the humidity cabinet, HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS are brought to a temperature between *T* and *T* + 4 °C, and kept at this temperature for at least 4 h before the humidity treatment starts.

Keep HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS and its parts, where the ENCLOSURE is classified as IPX0, in the humidity cabinet for at least 48 h.

Keep HEARING INSTRUMENTS and HEARING INSTRUMENT SYSTEMS and its parts, where the ENCLOSURE is designed to provide higher ingress protection against liquids, in the humidity cabinet for 168 h.

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

201.5.9.1 *APPLIED PARTS

Addition:

The HEARING INSTRUMENT is a TYPE B APPLIED PART in the HEARING INSTRUMENT SYSTEM. If any other parts have to be in contact with the PATIENT, those parts are also TYPE B APPLIED PARTS.

201.5.9.2 ACCESSIBLE PARTS

201.5.9.2.1 Test finger

Addition:

The tests as described in the general standard are additionally performed with the small finger probe shown in Figure 1 of IEC 60601-1-11:2010.

201.5.201 SOUND PRESSURE LEVEL

Any sound pressure level specified in this document is measured in decibels (dB) as described in IEC 60118-0:2015.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Replacement:

HEARING INSTRUMENTS are INTERNALLY POWERED, but may have connections to mains supplied equipment. The insulation between the SUPPLY MAINS and the HEARING INSTRUMENT shall be provided within the power supply, charger or other type of ACCESSORY.

The HEARING INSTRUMENT is classified a TYPE B APPLIED PART.

201.6.3 Protection against harmful ingress of water or particulate matter

Replacement:

See 201.11.6.5.

201.6.6 Mode of operation

Replacement:

HEARING INSTRUMENTS are classified for CONTINUOUS OPERATION.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.1 General

201.7.1.1 USABILITY of the identification, marking and documents

Replacement:

The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISK of poor USABILITY associated with the design of the HEARING INSTRUMENT'S identification, marking and documents.

The USABILITY of the identification, marking and ACCOMPANYING DOCUMENTS intended for the PATIENT shall be evaluated based on a PATIENT profile that includes basic school education.

Hearing instruments should be designed to be simple to use and not require reference to complex ACCOMPANYING DOCUMENTS.

Compliance shall be checked by inspection of the results of the RISK MANAGEMENT PROCESS.

201.7.1.2 Legibility of markings

Replacement:

The markings required by 7.2 and 7.3 shall be clearly legible under the following conditions:

– Safety signs and identification, on the HEARING INSTRUMENT except serial number, shall be clearly legible when it is placed in the hand of the PATIENT.
– The serial number and any other markings shall be legible utilizing an optical aid if necessary.

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.1 Minimum requirements for marking on HEARING INSTRUMENT

Replacement:

If the size of the HEARING INSTRUMENT does not allow affixation of all markings specified in 7.2, the markings shall be recorded in full in the ACCOMPANYING DOCUMENTS.

201.7.2.2 Identification

Replacement:

HEARING INSTRUMENTS shall be marked on the outside with:

– the name or trademark of the MANUFACTURER;
– a MODEL OR TYPE REFERENCE.

HEARING INSTRUMENTS shall be marked visibly on the outside or other user accessible location: