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REDLINE VERSION

TECHNICAL REPORT

colour inside

Summary of requirements and tests to products in the scope of IEC 60601-2-66

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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SUMMARY OF REQUIREMENTS AND TESTS FOR PRODUCTS IN THE SCOPE OF IEC 60601-2-66

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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The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a Technical Report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC 62809, which is a Technical Report, has been prepared by IEC technical committee 29: Electroacoustics.

This second edition cancels and replaces the first edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) introduction of the term FITTED OSPL90 (FITTED MAXIMUM OUTPUT SOUND PRESSURE LEVEL) (201.3.206 of IEC 60601-2-66:2019);

b) the allowable maximum output sound pressure level is now based on FITTED MAXIMUM OUTPUT SOUND PRESSURE LEVEL (201.9.6 of IEC 60601-2-66:2019).

c) ESSENTIAL PERFORMANCE is based on risk analysis (201.4.3).

The text of this Technical Report is based on the following documents:

Draft TR	Report on voting
29/1015/DTR	29/1019/RVDTR

Full information on the voting for the approval of this Technical Report 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 document, the following print types are used:

– requirements and definitions: roman type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site 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.

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.

INTRODUCTION

During the preparation of IEC 60601-2-66, members of the involved technical committee and working group voiced concerns about the complexity of the document and its structure as part of the IEC 60601 series. Members felt distracted from the technical content by this complexity during reviews of the document stages. There was also concern that groups in the hearing ~~instrument~~ aid community would have problems to understand and apply the standard and that this could be an issue with its acceptability.

In order to have a broad consensus for the new standard, it was agreed that the standard should be supported by this Technical Report, which should enable members of the community and the industry to have a basic understanding of the requirements of the standard, without the need to study the complete standard document and the documents that are referenced in it.

IEC 60601-2-66 was published to address the specific requirements for safety of hearing ~~instruments~~ aids, and it is entitled “Particular requirements for the basic safety and essential performance of hearing ~~instruments~~ aids and hearing ~~instruments~~ aid systems”. It was published because IEC 60601-1 is a general standard intended to address a wide range of medical electrical equipment – including large scale facilities such as MRI machines, for example – and thus has large sections that are not relevant to low-voltage, low power, subminiature hearing ~~instruments~~ aids.

If IEC 60601-2-66 was not published, test and regulatory organizations would probably have difficulty applying IEC 60601-1, because it does not contain specific guidance for hearing ~~instruments~~ aids. This Technical Report contains all the requirements from IEC 60601-2-66 which relate to hearing ~~instruments~~ aids and reduces discussion with those that do not relate to hearing ~~instruments~~ aids.

It includes specific references to the applicable requirements within IEC 60601-1, and it is suggested that hearing ~~instrument~~ aid designers and manufacturers along with test and regulatory organizations read this Technical Report as an overview of IEC 60601-2-66.

SUMMARY OF REQUIREMENTS AND TESTS FOR PRODUCTS IN THE SCOPE OF IEC 60601-2-66

1 Scope

This document, which is a Technical Report, provides an overview of the requirements and tests of IEC 60601-2-66 in combination with the applicable sections of IEC 60601-1, and the collateral standards of the IEC 60601 series.

NOTE The IEC 60601 series consists of three levels of standards: IEC 60601-1, known as the general standard, several IEC 60601-1-X documents, known as the collateral standards, and a series of particular standards covering requirements for specific types of equipment (IEC 60601-2-X).

It is intended to assist various groups involved in the product lifecycles process – like designers and suppliers – to get an overview of the basic requirements without studying all involved standard documents in detail. The table includes not all but just the more common requirements and tests.

It is crucial to understand that the summary in this document cannot serve as an input for a product requirement specification or as a test plan without consulting ~~the standard document~~ IEC 60601-2-66 itself. This document alone cannot be used to establish or assess compliance to ~~the standard~~ IEC 60601-2-66.

The summary in Table 1 below does not preclude the user from reading the referenced standards in their entirety for a thorough knowledge of the basic safety of hearing ~~instruments~~ aids and hearing ~~instrument~~ aid systems.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-66:~~2012~~2019, *Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing ~~instruments~~ aids and hearing ~~instrument~~ aid systems*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

4 Summary of requirements and tests

The reference column in Table 1 shows the clause number of IEC 60601-2-66:~~2012~~2019 and, if applicable, the reference to IEC 60601-1:2005, or other documents. References to the particular standard IEC 60601-2-66:~~2012~~2019 start with the number 201, while references to the general standard, IEC 60601-1:2005, start directly with the clause or subclause number.

Other documents will be referred to explicitly. Some detailed references, for example describing tools, are placed in the text instead of in the reference column.

Table 1 – Summary of requirements and tests

Reference	Subject	Requirements and tests
201.1.1 201.8	ACCESSORY	Requirements: ACCESSORIES TO HEARING ~~INSTRUMENTS~~ AIDS (e.g. remote-control units, audio streamers, battery chargers, power supplies) need to have documented proof of compliance to IEC 60065, IEC 60950-1, ~~IEC 60601-1~~ IEC 62368-1 or other applicable IEC safety standards. They form a HEARING ~~INSTRUMENT~~ AID SYSTEM when connected to the HEARING ~~INSTRUMENT~~ AID. Wherever this connection has an influence on the compliance to the requirements of IEC 60601-2-66, the HEARING ~~INSTRUMENT~~ AID has to pass the requirements while being connected to the ACCESSORY. If this connection results in additional requirements to the ACCESSORY, these requirements ~~have to~~ shall be fulfilled beyond the applicable IEC standards. Programming interfaces or ACCESSORIES in a clinical application are covered by IEC 60601 (all parts). For HEARING ~~INSTRUMENTS~~ AIDS that are supplied by an external power source: If a particular separate power supply is specified, then the relevant tests are performed with the HEARING ~~INSTRUMENTS~~ AIDS connected to it. If a generic separate power supply is specified, then the specification in the ACCOMPANYING DOCUMENTS is inspected. Tests: Inspection of ACCESSORY documentation, test configuration
201.4.1 201.4 Clause 4 Clause 5	Type tests	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. Testing conditions shall consider not just NORMAL USE but also reasonably foreseeable misuse. Misuse and faults shall be the subject and results of the RISK ANALYSIS. The instructions for use ~~have to~~ shall be considered in testing conditions. The equipment is tested under the least favorable working conditions.
4.2 4.5 ISO 14971	Risk management	Requirements: A RISK MANAGEMENT complying with ISO 14971 shall be performed. Where IEC 60601-2-66 specifies requirements addressing particular RISKS, alternative means of addressing these RISKS are acceptable provided that the MANUFACTURER can justify that the RESIDUAL RISKS are the same or lower. Tests: Inspection of the RISK MANAGEMENT FILE.
201.4.3 4.3	Essential performance	Requirements; After a careful consideration of the clauses within this document, it was decided that they all deal with BASIC SAFETY as defined in the general standard. Manufacturers have the ability to identify functions of HEARING AIDS which are considered ESSENTIAL PERFORMANCE in accordance with their RISK MANAGEMENT PROCESS.
4.4	Expected service life	Requirements: The MANUFACTURER shall state the EXPECTED SERVICE LIFE of the HEARING ~~INSTRUMENT~~ AID in the RISK MANAGEMENT FILE. Tests: Inspection of the RISK MANAGEMENT FILE.

Reference	Subject	Requirements and tests
4.8 4.9	Components	Requirements: Components the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings. The reliability of components that are used as MEANS OF PROTECTION shall be assessed. They shall comply with the applicable safety requirements of a relevant IEC or ISO standard (options see 4.8). Tests: Inspection and, where necessary, test.
7.1.3	Durability of markings	Requirements: Markings shall be removable only with a TOOL or by appreciable force and shall be sufficiently durable to remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE. Tests: Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit and then for 15 s with a cloth rag soaked with isopropyl alcohol.
201.7.1.2 201.7.2.1	Legibility of markings	Requirements: Markings shall be CLEARLY LEGIBLE when it is placed in the hand. The serial number and other markings shall be legible utilizing an optical aid if necessary. If the size of the HEARING ~~INSTRUMENT~~ AID does not allow affixation of all required markings, the markings shall be recorded in full in the ACCOMPANYING DOCUMENTS or instructions for use (IFU). Tests: Inspection and verification of the applicable requirements.
201.7.2.2 7.3.3 7.4.2 7.8.2	Markings	Requirements: HEARING ~~INSTRUMENTS~~ AIDS shall be marked with: – the name or trademark of the MANUFACTURER; – a MODEL OR TYPE REFERENCE. HEARING ~~INSTRUMENTS~~ AIDS shall be marked visibly on the outside or ~~inside when the battery drawer is open~~ at a user accessible location (e.g. battery drawer), with: – if needed: identification of right and left HEARING ~~INSTRUMENT~~ AID. Right = red. Left = blue; – serial number. HEARING ~~INSTRUMENTS~~ AIDS worn in the ear: The marking on the ~~instrument~~ HEARING AID may be reduced to the serial number and the identification of right and left. The type of battery and the mode of insertion shall be marked on HEARING ~~INSTRUMENTS~~ AIDS unless the design of the battery compartment prevents incorrect replacement of a battery Different positions of control devices and switches shall be indicated by figures, letters or other visual means. If the change of setting of a control could result in a RISK, such controls shall be provided with an indicating device or an indication of the direction in which the magnitude of the function changes. The color red shall be used only for emergency controls. Tests: Inspection and verification of the applicable requirements.

Reference	Subject	Requirements and tests
201.7.2.17	Protective packaging	Requirements: If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly. Tests: Inspection and verification of the applicable requirements.
201.7.8.1 201.7.9 7.6.1	ACCOMPANYING DOCUMENTS	Requirements: HEARING ~~INSTRUMENTS~~ AIDS shall be accompanied by instructions containing at least: – the purpose and INTENDED USE of the HEARING ~~INSTRUMENT~~ AID; – instructions for use, operating functions and a technical description; – easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate HEARING ~~INSTRUMENT~~ AID including all controls, visual information signals, and indicators, proper connection of the PATIENT to the HEARING ~~INSTRUMENT~~ AID, ACCESSORIES and other equipment; – identification of the HEARING ~~INSTRUMENT~~ AID: • name or trade name of the MANUFACTURER and an address to which the PATIENT can refer; • MODEL OR TYPE REFERENCE; – a list of detachable and replaceable parts as well as ACCESSORIES; – any restrictions on locations or environments in which the HEARING ~~INSTRUMENT~~ AID can be used; – identification of any known side effects associated with the use of HEARING ~~INSTRUMENT~~ AID that may warrant consultation with a physician e.g. accumulation of cerumen; – advice to the PATIENT to contact the MANUFACTURER or the MANUFACTURER's representative: • for assistance, if needed, in setting up, using or maintaining the HEARING ~~INSTRUMENT~~ AID or HEARING ~~INSTRUMENTS~~ AID SYSTEM; • to report unexpected operation or events; – a description and illustration on how to replace and/or recharge batteries; – colors of indicator lights and their meanings; – the meanings of the symbols used for marking (symbols see 7.6.2). – how to dispose of batteries of the HEARING ~~INSTRUMENTS~~ AIDS and of any part that may provide a RISK associated with the disposal; – information about cleaning and maintenance, where applicable: • the procedure to follow for washing the ear mould; • replacing tubing, filters and other replaceable parts; • storing the HEARING ~~INSTRUMENT~~ AID; • special adequate maintenance for rechargeable batteries; • information on how and where to obtain repair service; – if a HEARING ~~INSTRUMENTS~~ AIDS is difficult to retrieve from the ear canal a method to detect its location and to retrieve it shall be provided; – warning and safety notices in a specifically identified section of the instructions for use; if a warning or safety notice applies only to a specific instruction or action it should precede the instruction to which it applies; • for HEARING ~~INSTRUMENTS~~ AIDS in pediatric applications: Warning to keep small parts (HEARING ~~INSTRUMENTS~~ AIDS, batteries and detachable parts) that can be swallowed out of children's reach; ~~• for HEARING INSTRUMENTS able to provide more than 132 dB SPL: warning to the professional OPERATOR fitting the HEARING INSTRUMENT that there may be a RISK of impairing the remaining hearing of the PATIENT;~~ • for HEARING ~~INSTRUMENTS~~ AIDS that do not comply with requirements for explosive or oxygen-enriched atmospheres: warning not to use the HEARING ~~INSTRUMENTS~~ AIDS in such areas where there is danger of explosion;