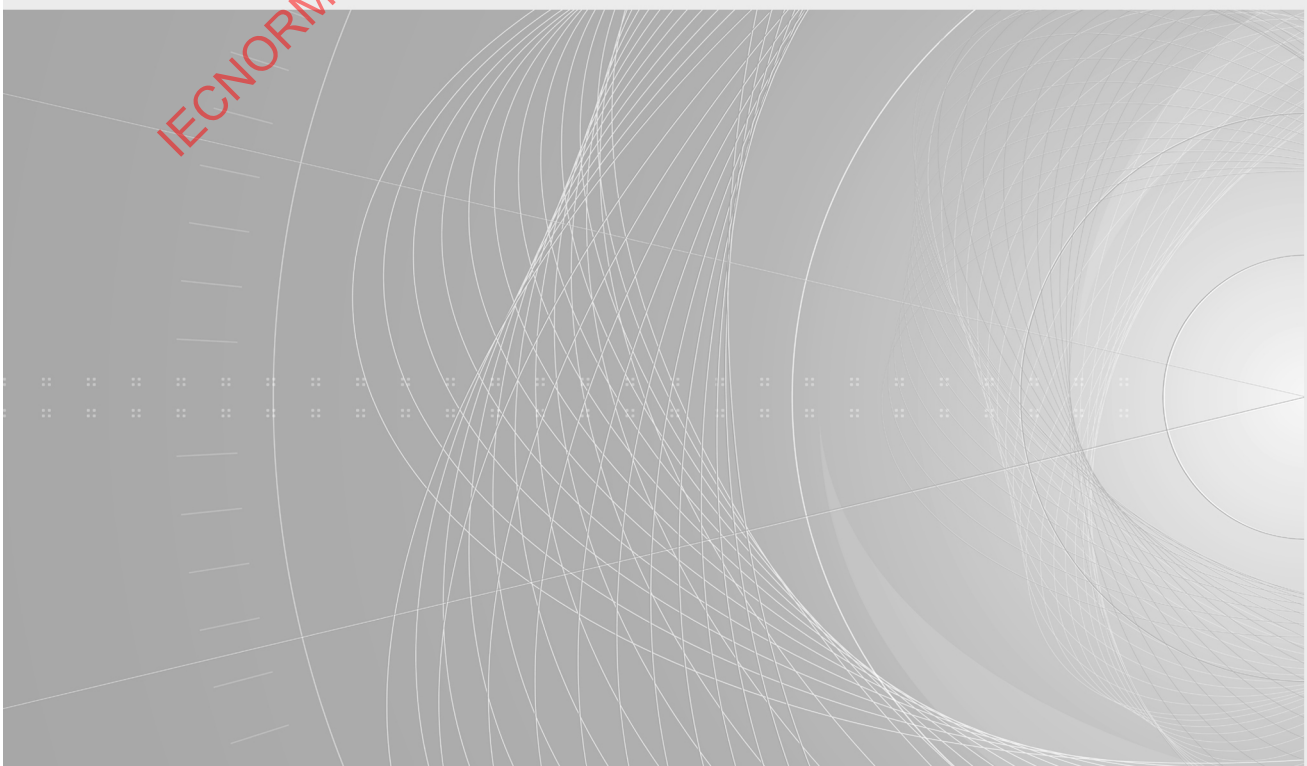
IEC TR 62809

Edition 2.0 2019-10

TECHNICAL REPORT

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



IEC TR 62809:2019-10(en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC TR 62809

Edition 2.0 2019-10

TECHNICAL REPORT

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.180.15; 17.140.50

ISBN 978-2-8322-7523-8

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

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.
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.

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.

A bilingual version of this publication may be issued at a later date.

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 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 aids, and it is entitled “Particular requirements for the basic safety and essential performance of hearing aids and hearing 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 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 aids. This Technical Report contains all the requirements from IEC 60601-2-66 which relate to hearing aids and reduces discussion with those that do not relate to hearing aids.

It includes specific references to the applicable requirements within IEC 60601-1, and it is suggested that hearing 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 IEC 60601-2-66 itself. This document alone cannot be used to establish or assess compliance to 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 aids and hearing 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 60601-2-66:2019, *Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing 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 60601-2-66:2019 and, if applicable, the reference to IEC 60601-1:2005, or other documents. References to the particular standard IEC 60601-2-66:2019 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 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 62368-1 or other applicable IEC safety standards. They form a HEARING AID SYSTEM when connected to the HEARING AID. Wherever this connection has an influence on the compliance to the requirements of IEC 60601-2-66, the HEARING AID has to pass the requirements while being connected to the ACCESSORY. If this connection results in additional requirements to the ACCESSORY, these requirements 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 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 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 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 AID in the RISK MANAGEMENT FILE. Tests: Inspection of the RISK MANAGEMENT FILE.
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.

Reference	Subject	Requirements and tests
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 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 AIDS shall be marked with: – the name or trademark of the MANUFACTURER; – a MODEL OR TYPE REFERENCE. HEARING AIDS shall be marked visibly on the outside or at a user accessible location (e.g. battery drawer), with: – if needed: identification of right and left HEARING AID. Right = red, Left = blue; – serial number. HEARING AIDS worn in the ear: The marking on the 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 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.
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 AIDS shall be accompanied by instructions containing at least: – the purpose and INTENDED USE of the HEARING 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 AID including all controls, visual information signals, and indicators, proper

		connection of the PATIENT to the HEARING AID, ACCESSORIES and other equipment; – identification of the HEARING 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 AID can be used; – identification of any known side effects associated with the use of HEARING 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 AID or HEARING 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 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 AID; • special adequate maintenance for rechargeable batteries; • information on how and where to obtain repair service; – if a HEARING 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 AIDS in pediatric applications: Warning to keep small parts (HEARING AIDS, batteries and detachable parts) that can be swallowed out of children's reach; • for HEARING AIDS that do not comply with requirements for explosive or oxygen-enriched atmospheres: warning not to use the HEARING AIDS in such areas where there is danger of explosion; • warning that the specific HEARING AID shall only be used by the intended person and not by others; • for HEARING AIDS with wireless transmission: warning to check first before using the HEARING AID SYSTEM in areas where electronics or wireless devices are restricted; • statement required about the special needs of particular PATIENT groups e.g. small children or mentally disabled persons; • warning about common conditions that could damage the HEARING AID such as dropping, immersing in liquid, strong electromagnetic fields or excessive heat; • other warnings that may result from the risk assessment, e.g. a warning if parts could remain in the ear and what to do; • the permissible environmental conditions of transport and storage of a HEARING AID after it has been removed from its protective packaging and subsequently between uses; • for each warning and safety sign, the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK; • if leakage from a battery would result in a RISK, a warning to remove the battery; • if the HEARING AID can be externally connected, a warning only to connect to equipment that conforms to relevant international safety standards;

Reference	Subject	Requirements and tests
		– permissible environmental conditions of transport and storage of a HEARING AID after it has been removed from its protective packaging and subsequently between uses; – the ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended; – the instructions for use shall be in a language that is acceptable to the intended PATIENT; – Warning to the HEARING AID PROFESSIONAL; • for HEARING AIDS able to provide more than 132 dB SPL: warning to the professional OPERATOR fitting the HEARING AID that there may be a RISK of impairing the remaining hearing of the PATIENT; • the developed SPL in the ears of children can be substantially higher than in average adults. RECD measured to correct target of fitted OSPL90 is recommended; Parts of the ACCOMPANYING DOCUMENTS may be provided electronically. If so, the RISK MANAGEMENT PROCESS shall include consideration of which information also needs to be provided as hard copy. Tests: Inspection and verification of the applicable requirements.
201.8 201.8.7 201.5.7	Protection against electrical HAZARDS	Requirements: HEARING AIDS that are normally used in a HOME HEALTHCARE ENVIRONMENT with connections to electrical equipment in compliance with the relevant standard IEC 60065, IEC 60950-1, IEC 62368-1 or other applicable IEC safety standards shall pass the PATIENT LEAKAGE CURRENT requirements of 100 µA RMS at 275 V AC, as described in 201.8.7. Tests: PATIENT LEAKAGE CURRENT of 201.8.7, measurement after the humidity treatment of 201.5.7 and the drop test of 201.15.3.4.
201.16 201.5.9.2.1	ACCESSIBLE PARTS	Requirements: The voltage to earth or to ACCESSIBLE PARTS other than HEARING AIDS shall not exceed 42,4 V peak AC or 60 V DC in NORMAL CONDITION or in SINGLE FAULT CONDITION. The DC limit of 60 V applies to DC with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies. The power shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential of to 2 V or more. Tests: Inspection of product documentation in case this inspection is not conclusive: measurement. If internal parts exceed these limits, access is tested by test finger (201.5.9.2.1); small finger probe (test pin (Figure 8 of IEC 60601-1:2005) and/or metal test rod (8.4.2).
201.8.4.2 201.8.7.4.8	Accessible contacts	Requirements: If an internally supplied HEARING AIDS rated at 4,5 V DC or less has ACCESSIBLE PARTS, the DC current flowing in a realistic worst-case configuration between those contacts shall not exceed 10 µA and the RISK ASSESSMENT shall cover the particular design and application. Tests: Measurement and inspection of the RISK ASSESSMENT
201.9	Mechanical hazards	Requirements: Rough surfaces, sharp corners and edges of HEARING AID and HEARING AID SYSTEMS (e.g. moulded edges, battery doors and connector flanges) that could cause injury of damage shall be avoided or covered. Test: inspection of the HEARING AID, HEARING AID SYSTEMS and the RISK MANAGEMENT FILE.

Reference	Subject	Requirements and tests
201.9.6 201.13 IEC 60118-0	Acoustic energy	Requirements: HEARING AIDS shall be designed in a way that users cannot be unintentionally exposed to a SPL above the fitted OSPL90 in NORMAL CONDITION. The acceptable level increase in SINGLE FAULT condition, which shall be evaluated in the RISK MANAGEMENT FILE. The fitted OSPL90 shall be indicated on either the HEARING AID or the fitting software or otherwise. The maximum deviation shall be evaluated in THE RISK MANAGEMENT FILE. HEARING AIDS with a possible MAXIMUM OUTPUT SOUND PRESSURE LEVEL of 132 dB SPL require a special warning notice for the HEARING AID PROFESSIONAL (see 201.7). Tests: Inspection of the RISK MANAGEMENT FILE
201.9.101	Entanglement	Requirements: Cables and lanyards of HEARING AIDS or ACCESSORIES worn by the PATIENT around the neck shall not pose a RISK of injury or strangulation. The disconnection force shall be no greater than 30 N. Tests: Application of the pull force.
201.9.102	Parts remaining in the ear canal	Requirements: A HEARING AID that can be worn in the ear canal shall be safely retrievable by the PATIENT. HEARING AIDS shall be designed in a way that parts do not come loose during use, insertion and retrieval from the ear canal. Any part which is exposed to a pull force during the removal of a HEARING AID from the ear canal shall resist a force of at least 3 N without coming loose from the HEARING AID. Tests: Application of the pull force test, inspection of user instructions.
201.10 10.4	LED	Requirements: LEDs shall be class I according to IEC 60825-1. Tests: Inspection of the component specification and the circuitry.
201.11 201.13	Maximum temperature	Requirements: Maximum temperature of the HEARING AIDS shall not exceed 41 °C in normal use (in case of higher temperature, see 201.11.1.1) and 48 °C under fault conditions. If the hearing aid can operate in ambient temperatures above 43 °C, the maximum case temperature is permitted to be equal to the ambient temperature. Tests: Inspection of energy source and circuitry causing self-heating of the hearing aid. In case of doubt, a measurement shall be performed: the maximum temperature of the HEARING AID shall not exceed 43 °C, when tested in ambient temperature of 25 °C to 35 °C.
201.11.6.5	Ingress of water	Requirements: If the RISK ASSESSMENT requires protection against harmful ingress of water or particulate matter, the IP class of the HEARING AID shall be not less than the level required for safe operation as detailed in IEC 60529. Tests: Apply IEC 60529.

Reference	Subject	Requirements and tests
201.11.6.6	Cleaning	Requirements: HEARING AIDS and HEARING AID SYSTEMS and their parts and ACCESSORIES shall be capable of withstanding, without damage or deterioration, the cleaning or disinfection processes (such as cerumen removal), as specified in the instructions for use. Tests: Evaluate the effects of multiple cleanings during the EXPECTED SERVICE LIFE of the HEARING AIDS and HEARING AID SYSTEMS, their parts and ACCESSORIES and assure that no unacceptable RISK will occur. The results of the evaluation shall be documented in the RISK MANAGEMENT FILE.
11.6.8	Compatibility with substances	Requirements: When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with compatibility with substances used with the HEARING AID. Tests: Inspection of the RISK MANAGEMENT FILE.
11.7	Biocompatibility	Requirements: HEARING AIDS shall be biocompatible. Tests: Assessment and documentation according to the guidance and principles given in ISO 10993 (all parts).
201.7.1.1 201.12.2 12.2 IEC 60601-1-6	Usability	Requirements: USABILITY ENGINEERING PROCESS according to IEC 60601-1-6 and IEC 62366 shall be performed. The results have to be considered in the design of a product, the labelling and instructions. HEARING AIDS should be designed to be simple to use and not require reference to complex instructions. Typical PRIMARY OPERATING FUNCTIONS are: – critical functions: • placing and removing the HEARING AID; • fitting a HEARING AID; • testing of essential physical HEARING AID parameters; – frequently used functions: • changing battery; • cleaning; • switching on /off; • adjust volume, program and other essential parameters. Tests: Inspection of the results of the USABILITY ENGINEERING PROCESS and the instructions; trial test the product if necessary.
201.12.4.4	Incorrect output	Requirements: When a control adjusts the intended maximum power output, output power shall not increase if the control is disconnected or defective. Software controlled maximum power settings shall not exceed the selected value as a result of corrupt data transfer between programmer and HEARING AID. Tests: Inspection of circuitry, firmware, software and the RISK MANAGEMENT FILE; trial test where necessary.

Reference	Subject	Requirements and tests
201.13 13 11.3	HAZARDOUS SITUATIONS and fault conditions	Requirements: The following HAZARDOUS SITUATIONS shall not occur: – emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities; – deformation of ENCLOSURES to such an extent that risks result; – temperatures of HEARING AIDS that are likely to be touched shall not exceed 43 °C. - exceeding the allowable values for “other components and materials” identified in Table 22 of the general standard times 1,5 minus 12,5 °C. Tests: Inspection of circuit, application of faults. Faults need not be applied if a) the construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J, or b) if parts are completely contained within a fire enclosure according to the general standard. See 201.13.2.1 for the description of SINGLE FAULT and NORMAL CONDITIONS. NOTE The requirements to HEARING AIDS that are intended to be used in oxygen enriched or explosive atmospheres are not contained in IEC 60601-2-66.

Reference	Subject	Requirements and tests
201.14 14	Software	Requirements: – Embedded and fitting software shall conform to IEC 62304. – The classification of software according to IEC 62304 shall be the result of the RISK ASSESSMENT. Aspects to be considered beyond the requirements of IEC 62304: 14.2 Documentation The required processes for RISK MANAGEMENT and software development shall be correctly implemented and maintained. Documentation that the PROCESS steps have been performed needs to be filed in the RISK MANAGEMENT FILE. A document control system needs to be in place. 14.3 RISK MANAGEMENT plan In addition to elements of the RISK MANAGEMENT plan required by ISO 14971, a PEMS VALIDATION plan is required. 14.6.1 Identification of known and foreseeable HAZARDS PEMS have extra initiating causes for HAZARDS. 14.11 PEMS VALIDATION PEMS VALIDATION is intended to assure that the right product is built. Unexpected interactions between functions might occur that can only be discovered by validation. It can include tests for a high volume of data, heavy loads or stresses, human factors, security, performance, configuration compatibility, fault testing, documentation and safety. Independence is needed to avoid conflicts of interest and because the assumptions of the designer should not influence or limit the extent of the PEMS VALIDATION. Examples of level of independence include: – separate person; – separate management; – separate organization. Tests: Application of the requirements in Clause 201.14 by inspection of the RISK MANAGEMENT FILE. Compliance with the IEC 62304 software design and the RISK MANAGEMENT PROCESS by inspection of external or internal audit reports or certificates.
201.15.2	Serviceability	Requirements: Parts of HEARING AIDS subject to mechanical wear, electrical and environmental degradation or ageing that could result in an unacceptable RISK if allowed to continue unchecked for too long a period shall be accessible for inspection, replacement and maintenance. Tests: Inspection of such parts and their location.