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BSI Standards Publication

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

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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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TECHNICAL REPORT

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
29/776/DTR	29/791/RVC

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 standard, 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- withdrawn,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 instrument 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, and it is entitled “Particular requirements for the basic safety and essential performance of hearing instruments and hearing instruments 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.

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. This Technical Report contains all the requirements from IEC 60601-2-66 which relate to hearing instruments, and reduces discussion with those that do not relate to hearing instruments.

It includes specific references to the applicable requirements within IEC 60601-1, and it is suggested that hearing instrument 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 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 itself. This Technical Report alone cannot be used to establish or assess compliance to the standard.

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

3 Summary of requirements and tests

The reference column in Table 1 shows the clause number of IEC 60601-2-66:2012 and, if applicable the reference to IEC 60601-1:2005, or other documents. References to the particular standard, IEC 60601-2-66:2012 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	<p>Requirements:</p> <p>ACCESSORIES to HEARING INSTRUMENTS (e.g. remote control units, audio streamers, battery chargers, power supplies) need to have documented proof of compliance to IEC 60065, IEC 60950-1, the IEC 60601-1 or other applicable IEC safety standards. They form a HEARING INSTRUMENT SYSTEM when connected to the HEARING INSTRUMENT. Wherever this connection has an influence on the compliance to the requirements of IEC 60601-2-66 the HEARING INSTRUMENT 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 be fulfilled beyond the applicable IEC standards.</p> <p>Programming interfaces or ACCESSORIES in a clinical application are covered by IEC 60601.</p> <p>For HEARING INSTRUMENTS 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 connected to it. If a generic separate power supply is specified, then the specification in the ACCOMPANYING DOCUMENTS is inspected.</p> <p>Tests:</p> <p>Inspection of ACCESSORY documentation, test configuration</p>
201.4.1 201.4 4 5	TYPE TESTS	<p>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.</p> <p>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 be considered in testing conditions.</p> <p>The equipment is tested under the least favourable working conditions.</p>
4.2 4.5 ISO 14971	RISK MANAGEMENT	<p>Requirements:</p> <p>A RISK MANAGEMENT complying with ISO 14971 shall be performed.</p> <p>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.</p> <p>Tests:</p> <p>Inspection of the RISK MANAGEMENT FILE</p>
4.4	EXPECTED SERVICE LIFE	<p>Requirements:</p> <p>The MANUFACTURER shall state the EXPECTED SERVICE LIFE of the HEARING INSTRUMENT in the RISK MANAGEMENT FILE.</p> <p>Tests:</p> <p>Inspection of the RISK MANAGEMENT FILE</p>
4.8 4.9	Components	<p>Requirements:</p> <p>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).</p> <p>Tests:</p> <p>Inspection and, where necessary, test.</p>

Reference	Subject	Requirements and tests
7.1.3	Durability of markings	<p>Requirements:</p> <p>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.</p> <p>Tests:</p> <p>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.</p>
201.7.1.2 201.7.2.1	Legibility of markings	<p>Requirements:</p> <p>Markings shall be CLEARLY LEGIBLE when it is placed in the hand.</p> <p>The serial number and other markings shall be legible utilizing an optical aid if necessary.</p> <p>If the size of the HEARING INSTRUMENT does not allow affixation of all required markings, the markings shall be recorded in full in the instructions.</p> <p>Tests:</p> <p>Inspection and verification of the applicable requirements.</p>
201.7.2.2 7.3.3 7.4.2 7.8.2	Markings	<p>Requirements:</p> <p>HEARING INSTRUMENTS shall be marked with:</p> <ul style="list-style-type: none"> – the name or trademark of the MANUFACTURER; – a MODEL OR TYPE REFERENCE. <p>HEARING INSTRUMENTS shall be marked visibly on the outside or inside when the battery drawer is open, with:</p> <ul style="list-style-type: none"> – If needed: Identification of right and left HEARING INSTRUMENT. Right = red. Left = blue; – serial number. <p>HEARING INSTRUMENTS worn in the ear: The marking on the instrument may be reduced to the serial number and the identification of right and left.</p> <p>The type of battery and the mode of insertion shall be marked on HEARING INSTRUMENTS unless the design of the battery compartment prevents incorrect replacement of a battery</p> <p>Different positions of control devices and switches shall be indicated by figures, letters or other visual means.</p> <p>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.</p> <p>The colour red shall be used only for emergency controls.</p> <p>Tests:</p> <p>Inspection and verification of the applicable requirements.</p>
201.7.2.17	Protective packaging	<p>Requirements:</p> <p>If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly.</p> <p>Tests:</p> <p>Inspection and verification of the applicable requirements.</p>

Reference	Subject	Requirements and tests
201.7.8.1 201.7.9 7.6.1	ACCOMPANYING DOCUMENTS	<p>Requirements:</p> <p>HEARING INSTRUMENTS shall be accompanied by instructions containing at least:</p> <ul style="list-style-type: none"> – the purpose and INTENDED USE of the HEARING INSTRUMENT; – 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 including all controls, visual information signals, and indicators, proper connection of the PATIENT to the HEARING INSTRUMENT, ACCESSORIES and other equipment; – identification of the HEARING INSTRUMENT: <ul style="list-style-type: none"> • 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 can be used; – identification of any known side effects associated with the use of HEARING INSTRUMENT 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: <ul style="list-style-type: none"> • for assistance, if needed, in setting up, using or maintaining the HEARING INSTRUMENT or HEARING INSTRUMENTS SYSTEM; • to report unexpected operation or events; – a description and illustration on how to replace and/or recharge batteries; – colours 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 and of any part that may provide a RISK associated with the disposal; – information about cleaning and maintenance, where applicable: <ul style="list-style-type: none"> • the procedure to follow for washing the ear mould; • replacing tubing, filters and other replaceable parts; • storing the HEARING INSTRUMENT; • special adequate maintenance for rechargeable batteries; • information on how and where to obtain repair service; – if a HEARING INSTRUMENT 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: <ul style="list-style-type: none"> • for HEARING INSTRUMENTS in paediatric applications: Warning to keep small parts (HEARING INSTRUMENTS, 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 that do not comply with requirements for explosive atmospheres: warning not to use the HEARING INSTRUMENT in areas where there is danger of explosion; • warning that the specific HEARING INSTRUMENT must only be used by the intended person and not by others; • for HEARING INSTRUMENTS with wireless transmission: warning to check first before using the HEARING 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

Reference	Subject	Requirements and tests
		<p>persons;</p> <ul style="list-style-type: none"> • warning about common conditions that could damage the HEARING INSTRUMENT such as dropping, immersing in liquid, strong electromagnetic fields or excessive heat; • if leakage from a battery would result in a RISK, a warning to remove the battery; • if the HEARING INSTRUMENT can be externally connected, a warning only to connect to equipment that conforms to relevant international safety standards; • other warnings that may result from the RISK ASSESSMENT, e.g. a warning if parts could remain in the ear and what to do; • 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; <p>– permissible environmental conditions of transport and storage of a HEARING INSTRUMENT after it has been removed from its protective packaging and subsequently between uses;</p> <p>– 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;</p> <p>– the instructions for use shall be in a language that is acceptable to the intended PATIENT.</p> <p>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.</p> <p>Tests:</p> <p>Inspection and verification of the applicable requirements.</p>
201.8 201.8.7 201.5.7	Protection against electrical HAZARDS	<p>Requirements:</p> <p>HEARING INSTRUMENTS 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, or other applicable IEC safety standards shall pass the PATIENT LEAKAGE CURRENT requirements of 100 μA rms at 275 V a.c. as described in 201.8.7.</p> <p>Tests:</p> <p>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.</p>
201.16 201.5.9.2.1	ACCESSIBLE PARTS	<p>Requirements:</p> <p>The voltage to earth or to ACCESSIBLE PARTS other than HEARING INSTRUMENTS shall not exceed 42,4 V peak a.c. or 60 V d.c. in NORMAL CONDITION or in SINGLE FAULT CONDITION. The d.c. limit of 60 V applies to d.c. with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies. The energy shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential up to 2 V.</p> <p>Tests:</p> <p>Inspection of product documentation, in case this inspection is not conclusive, measurement.</p> <p>If internal parts exceed these limits, access is tested by test finger (201.5.9.2.1); small finger probe (Figure 1of IEC 60601-1-11:2010.), test pin (Figure 8 of IEC 60601-1:2005) and/or metal test rod (8.4.2).</p>
201.8.4.2 201.8.7.4.8	Accessible contacts	<p>Requirements:</p> <p>If an internally supplied HEARING INSTRUMENTS rated at 1,6 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.</p> <p>Tests:</p> <p>Measurement and inspection of the RISK ASSESSMENT</p>

Reference	Subject	Requirements and tests
201.9	MECHANICAL HAZARDS	Requirements: Rough surfaces, sharp corners and edges of HEARING INSTRUMENT and HEARING INSTRUMENT SYSTEMS (e.g. moulded edges, battery doors and connector flanges) shall be avoided or covered. Test: inspection of the HEARING INSTRUMENT, HEARING INSTRUMENT SYSTEMS and the RISK MANAGEMENT FILE.
201.9.6 201.13 IEC 60118-7:2005	Acoustic energy	Requirements: HEARING INSTRUMENTS shall be designed in a way that users cannot be unintentionally exposed to a sound pressure level above 132 dB in NORMAL and SINGLE FAULT CONDITION. Tests: Inspection of circuitry, firmware and software as applicable. Test in normal use and under SINGLE FAULT CONDITION. Measurements of sound pressure level are described in IEC 60118-7:2005
201.9.101	Entanglement	Requirements: Cables and lanyards of HEARING INSTRUMENTS 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 INSTRUMENT that can be worn in the ear canal shall be safely retrievable by the PATIENT. HEARING INSTRUMENTS 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 INSTRUMENT from the ear canal shall resist a force of at least 3 N without coming loose from the instrument. 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 INSTRUMENTS shall not exceed 41 °C in normal use (in case of higher temperature, see 201.11.1.1) and 50 °C under fault conditions. Tests: Inspection of energy source and circuitry. In case of doubt, a measurement shall be performed.
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 INSTRUMENT 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	<p>Requirements:</p> <p>HEARING INSTRUMENTS and HEARING INSTRUMENTS 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.</p> <p>Tests:</p> <p>Evaluate the effects of multiple cleanings during the EXPECTED SERVICE LIFE of the HEARING INSTRUMENTS and HEARING INSTRUMENTS 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.</p>
11.6.8	Compatibility with substances	<p>Requirements:</p> <p>When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with compatibility with substances used with the HEARING INSTRUMENT.</p> <p>Tests:</p> <p>Inspection of the RISK MANAGEMENT FILE.</p>
11.7	Biocompatibility	<p>Requirements:</p> <p>HEARING INSTRUMENTS shall be biocompatible.</p> <p>Tests:</p> <p>Assessment and documentation according to the guidance and principles given in the ISO 10993 series.</p>
201.7.1.1 201.12.2 12.2 IEC 60601-1-6	Usability	<p>Requirements:</p> <p>USABILITY ENGINEERING PROCESS according to IEC 60601-1-6 shall be performed. The results have to be considered in the design of a product, the labelling and instructions.</p> <p>HEARING INSTRUMENTS should be designed to be simple to use and not require reference to complex instructions.</p> <p>Typical PRIMARY OPERATING FUNCTIONS are:</p> <ul style="list-style-type: none"> – critical functions: <ul style="list-style-type: none"> • placing and removing the HEARING INSTRUMENT; • fitting a HEARING INSTRUMENT; • testing of essential physical HEARING INSTRUMENT parameters; – frequently used functions: <ul style="list-style-type: none"> • changing battery; • cleaning; • switching on /off; • adjust volume, program and other essential parameters. <p>Tests:</p> <p>Inspection of the results of the USABILITY ENGINEERING PROCESS and the instructions; trial test the product if necessary.</p>
201.12.4.4	Incorrect output	<p>Requirements:</p> <p>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 INSTRUMENT.</p> <p>Tests:</p> <p>Inspection of circuitry, firmware, software and the RISK MANAGEMENT FILE; trial test where necessary.</p>

Reference	Subject	Requirements and tests
12.4.3	Incorrect output	Requirements: The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accidental selection of an excessive output value. Tests: Inspection of the RISK MANAGEMENT FILE.
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 INSTRUMENTS that are likely to be touched, exceeding 50 °C when measured and adjusted as described in 201.11.1.3 of the general standard; – 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 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 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 INSTRUMENTS that are intended to be used in oxygen enriched or explosive atmospheres are not contained in this particular standard.

Reference	Subject	Requirements and tests
201.14 14	Software	<p>Requirements:</p> <ul style="list-style-type: none"> – 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. <p>Aspects to be considered beyond the requirements of IEC 62304:</p> <p>14.2 Documentation</p> <p>The required processes for RISK MANAGEMENT and software development have to be correctly implemented and maintained. Documentation that the PROCESS steps have been performed needs to be filed in the RISK MANAGEMENT FILE.</p> <p>A document control system needs to be in place.</p> <p>14.3 RISK MANAGEMENT plan</p> <p>In addition to elements of the RISK MANAGEMENT plan required by ISO 14971, a PEMS VALIDATION plan is required.</p> <p>14.6.1 Identification of known and foreseeable HAZARDS</p> <p>PEMS have extra initiating causes for HAZARDS.</p> <p>14.11 PEMS VALIDATION</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> – separate person; – separate management; – separate organization. <p>Tests:</p> <p>Application of the requirements in 201.14.2 to 201.14.13 (inclusive), 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.</p>
201.15.2	Serviceability	<p>Requirements:</p> <p>Parts of HEARING INSTRUMENTS 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.</p> <p>Tests:</p> <p>Inspection of such parts and their location.</p>

Reference	Subject	Requirements and tests
201.15.3	Mechanical strength	<p>Requirements:</p> <p>HEARING INSTRUMENTS or its parts shall have adequate mechanical strength and shall not result in an unacceptable RISK due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.</p> <p>Mechanical design requirements for instruments intended for use by infants under 36 months:</p> <p>a) battery doors shall be constructed to:</p> <ul style="list-style-type: none"> • require a TOOL to remove the battery, or • require a force of at least 10 N in the least favourable direction to remove the battery, <p>b) any detachable part of the HEARING INSTRUMENT (e.g. ear hook, tube, type plate, programming cover) shall not be removable:</p> <ul style="list-style-type: none"> • without a TOOL, or • with a force lower than 10 N in the direction of least resistance. <p>Tests:</p> <p>Inspection of the product and the application of the described forces.</p>
201.15.3.4	Drop test	<p>Requirement:</p> <p>HEARING INSTRUMENTS shall not result in an unacceptable RISK as a result of a free fall, such as increased LEAKAGE CURRENT or mechanical hazards.</p> <p>Test:</p> <p>The sample to be tested is allowed to fall freely once from each of six different starting orientations from 1,5 m height onto a hard wood surface.</p>
201.15.3.7	Environmental influences	<p>Requirements:</p> <p>The selection and treatment of materials used in the construction of HEARING INSTRUMENTS shall take account of the INTENDED USE, the EXPECTED SERVICE LIFE and the conditions for transport and storage.</p> <p>The HEARING INSTRUMENTS shall be so designed and constructed that during its EXPECTED SERVICE LIFE any corrosion, ageing, mechanical wear, or degradation of biological materials due to the influence of moisture, sweat, humidity, hair care products or toiletries shall not reduce its mechanical properties in a way that results in an unacceptable RISK.</p> <p>Tests:</p> <p>Inspection of HEARING INSTRUMENTS, the ACCOMPANYING DOCUMENTS and of the specifications of materials used, of the processing specifications for these materials and relevant tests or calculations.</p>
201.15.4.3.1	Housing	<p>Requirements:</p> <p>Battery compartments shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in a HAZARDOUS SITUATION.</p> <p>If a HAZARDOUS SITUATION might develop by the incorrect connection or replacement of a battery, the equipment shall be fitted with a means of preventing incorrect polarity.</p> <p>Tests:</p> <p>Inspection of circuit and construction.</p>
15.4.3.3	Overcharging	<p>Requirements:</p> <p>Where overcharging of any battery could result in an unacceptable RISK, the design shall prevent overcharging.</p> <p>Tests:</p> <p>Inspection of the design documentation.</p>

Reference	Subject	Requirements and tests
201.15.4.3.101	Batteries	<p>Requirements:</p> <p>Batteries, used to supply HEARING INSTRUMENTS, shall comply with the relevant international standards. The design of the electronic circuit shall avoid overheating of a wrongly inserted battery above 50 °C.</p> <p>Tests:</p> <p>Inspection of circuit and construction, if necessary testing. Inspection of the instructions for use.</p>
201.17	Electromagnetic compatibility	<p>Requirements:</p> <p>The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the introduction by the HEARING INSTRUMENT of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment and systems.</p> <p>Tests:</p> <p>Electromagnetic compatibility is tested according to IEC 60118-13. If the HEARING INSTRUMENT has a wireless transmitter, emissions are furthermore tested according to relevant international radio standards.</p> <p>Inspection of the RISK MANAGEMENT FILE.</p>

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- [1] IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements*
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 - [4] IEC 60601 (all parts), *Medical electrical equipment*
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 - [11] IEC 62304, *Medical device software – Software life-cycle processes*
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