

American National Standard



ANSI/AAMI CI86:2017

Cochlear implant systems:
Requirements for safety,
functional verification,
labeling and reliability
reporting

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting

Approved 15 December 2016 by
AAMI

Approved 6 January 2017 by
American National Standards Institute, Inc.

Abstract: This standard establishes minimum requirements for those active implantable medical devices known as cochlear implants or cochlear prostheses, which are intended to treat hearing impairment by means of electrical stimulation of the cochlea. Devices that treat hearing impairment other than by including electrical stimulation of the cochlea are not covered by this standard. This standard applies to the electrical stimulation component(s) of combination devices that treat hearing impairment using multiple means, including electrical stimulation. The tests specified in this standard are industry-accepted tests and are to be carried out on samples of devices to show compliance. This standard is also applicable to non-implantable parts and accessories of the devices, including fitting and diagnostic components. General and specific requirements are provided with regard to design verification, post-implantation device testing, reliability assessment and reporting, packaging and labeling, protections of the patient associated with design issues and device malfunctions, and protections of the device associated with environmental challenges arising from transport, storage, handling during implantation, unrelated-medical treatments, and normal use.

Keywords: cochlear implants, cochlear prosthesis, medical device

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The transition period for voluntary compliance with this standard is indicated below.

- o Design and test requirements (transition period is 2 years):
 - For devices or changes to devices approved prior to publication of standard, conformance to this standard is optional.
 - For devices or changes approved during the transition period, conformance will be negotiated between each manufacturer and the regulatory agency.
 - For new devices or designs marketed after the transition period, conformance to this standard is mandatory if a cochlear manufacturer intends to claim compliance to this standard.
- o Reliability reporting:
 - For all implantable components (both currently marketed and no longer distributed devices), the transition period for reporting as specified in this standard is 2 years from publication.
 - For implantable components that will be introduced after publication, the transition period for reporting as specified in this standard is 1 year.
 - For all sound processors (reporting as specified in Section 11), the transition period for reporting as specified in this standard is 2 years from publication.

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website through the link below, this glossary listing gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation Cochlear Implant Committee

This standard was developed by the AAMI Cochlear Implant Committee. Committee approval of the standard does not necessarily mean that all committee members voted for its approval.

At the time this standard was published, the **AAMI Cochlear Implant Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

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Foreword

This standard was developed by the AAMI Cochlear Implant Committee and establishes minimum safety and performance requirements for cochlear implants based on industry-accepted test methods. It is intended to assist manufacturers in testing and labeling their devices and in reporting device system reliability to the professional health care community and public. In turn, such uniformity and consistency should facilitate more informed decision making by health care professionals, potential cochlear implant patients, and parents of potential pediatric cochlear implant recipients, when selecting applicable device systems.

Cochlear implant systems consist of an implantable device that electrically stimulates the inner ear to produce perceptions of sound in patients with significantly impaired acoustic hearing and external devices that convert acoustic sound signals to electrical signals, communicate electromagnetically with the implant, and program the device. In the United States, cochlear implant systems are medical devices and, under the Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of May 28, 1976, are subject to regulation by the U.S. Food and Drug Administration (FDA). Such regulation includes, but is not limited to, FDA requirements for premarket approval (Section 515 of the Act) and medical device reporting.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the standard. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments and knowledge gained from field experience with the devices. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the American National Standard, *Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting* (ANSI/AAMI CI86:2017), but it does provide important information about the development and intended use of the document.

Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting

1 Scope

This standard specifies requirements, test procedures, methods and labeling for active implantable medical devices intended to treat hearing impairment by means of electrical stimulation of the cochlea. Such devices are referred to as cochlear implants or cochlear prostheses. This standard is also applicable to non-implantable parts and accessories of the devices, including fitting and diagnostic components.

A cochlear implant system can be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but some requirements for non-implantable parts and accessories must be specified if they could affect the safety or performance of the implantable part.

Devices that treat hearing impairment exclusively by means other than direct electrical stimulation are not covered by this standard (e.g., hearing aids, bone conduction devices, middle ear prostheses). For devices that treat hearing impairment using combined electrical and acoustic stimulation, only the components relevant to electrical stimulation are covered by this standard. The acoustic stimulation is covered by other relevant standards. For devices that deliver medicinal substances and are consequently combination products for regulatory purposes, this standard covers only the components relevant to electrical stimulation.

The tests specified in this standard serve two purposes:

- a) To demonstrate compliance with specific requirements in the standard (type tests) and
- b) To demonstrate functional performance of the system and/or subsystem components at specified reliability levels within known confidence limits (reliability tests)

The sample sizes and selection methods vary across the tests, depending on the purpose of the test, the degree of patient risk associated with failure of the component being tested, and the desired degree of confidence for the test.

The electrical, mechanical, and thermal characteristics of the implantable part shall be determined either by the appropriate method detailed in this particular standard or by another method demonstrated to have accuracy equal to, or better than, the method specified. In the case of dispute, the method detailed in this particular standard shall apply.

This standard requires the reporting of information regarding the design, operation, testing, and reliability of the implantable and non-implantable components of the cochlear implant system, including accessories required for or which extend the operation of the system. All such information shall be considered confidential to the manufacturer unless the standard states specifically that the information is for broader distribution and the standard provides detailed requirements for that broader distribution.

Throughout this standard, descriptive or explanatory information is included with the text describing requirements and tests. The information contained in notes should be considered in the implementation of tests and/or in the interpretation of results.

This standard does not address all of the appropriate aspects of wireless technology incorporated into cochlear implant systems. The standard does include some tests for specific aspects of wireless functionality of the system and its components.

This standard does not address the clinical/audiological performance data that a manufacturer might include as part of a regulatory submission to support the safety and effectiveness of a device.

2 Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of this standard. As designated by footnotes, some of these normative references apply in entirety to this standard, whereas only portions of the remaining normative references apply to this standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative reference referred to applies. AAMI maintains a register of currently valid AAMI technical documents.

- 2.1 AAMI TIR16775:2014, *Packaging for terminally sterilized medical devices—Guidance on the application of ISO 11607-1 and ISO 11607-2* *
- 2.2 ANSI/AAMI/ISO 10993-1, *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process* **
- 2.3 ANSI/AAMI/ISO 11607-1, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging* **
- 2.4 ANSI/AAMI/ISO 11607-2, *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes* **
- 2.5 AS 1647.2-1992, *Children's toys (Safety requirements)—Constructional requirements* *
- 2.6 AS/NZS ISO 8124.1 *Safety of toys, Part 1: Safety aspects related to mechanical and physical properties* *
- 2.7 ASTM F2052, *Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment* **
- 2.8 ASTM F2119, *Standard test method for evaluation of MR image artifacts from passive implant* **
- 2.9 ASTM F2182, *Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging* **
- 2.10 ASTM F2213, *Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment* **
- 2.11 ASTM F2503, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment* **
- 2.12 ASTM F963-11, *Standard consumer safety specification for toy safety* *
- 2.13 EN 13185, *Non-destructive testing—Leak testing—Tracer gas method* **
- 2.14 EN 1593, *Non-destructive testing—Leak testing—Bubble emission techniques* **
- 2.15 EN 45502-2-1, *Active Implantable Medical Devices—Part 2-1: Particular Requirements For Active Implantable Medical Devices Intended To Treat Bradyarrhythmia (Cardiac Pacemakers)* *

* Certain provisions of this normative reference constitute provisions of this standard, as specified in the text of this standard.

** All provisions of this normative reference constitute provisions of this standard.

- 2.16** EN 60068-2-1, *Environmental testing—Part 2-1: Tests—Test A: Cold* *
- 2.17** IEC 60068-2-14, *Environmental testing—Part 2-14: Tests—Test N: Change of temperature* *
- 2.18** IEC 60068-2-2, *Environmental testing—Part 2-2: Tests—Test B: Dry heat* *
- 2.19** IEC 60068-2-27, *Environmental testing—Part 2-27: Tests—Test Ea and guidance: Shock* **
- 2.20** IEC 60068-2-30, *Environmental testing—Part 2-30: Tests—Test Db: Damp heat, cyclic (12 h + 12 h cycle)* **
- 2.21** IEC 60068-2-31, *Environmental testing—Part 2-31: Tests—Test Ec: Rough handling shocks, primarily for equipment-type specimens* *
- 2.22** IEC 60068-2-47, *Environmental testing—Part 2-47: Test—Mounting of specimens for vibration, impact and similar dynamic tests* **
- 2.23** IEC 60068-2-64, *Environmental testing—Part 2-64: Tests—Test Fh: Vibration, broadband random and guidance* **
- 2.24** IEC 60068-2-75, *Environmental testing—Part 2-75: Tests—Test Eh: Hammer tests* **
- 2.25** IEC 60086-4, *Primary batteries—Part 4: Safety of lithium batteries* *
- 2.26** IEC 60118-0, *Electroacoustics—Hearing aids—Part 0: Measurement of the performance characteristics of hearing aids* *
- 2.27** IEC 60118-15:2012, *Electroacoustics—Hearing aids—Part 15: Methods for characterizing signal processing in hearing aids with a speech-like signal* *
- 2.28** IEC 60529, *Degrees of protection provided by enclosures (IP code) [including correction 3] Edition 2.2* **
- 2.29** IEC 60601-1, *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance* **
- 2.30** IEC 60601-1-11, *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* **
- 2.31** IEC 60601-1-2, *Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic disturbances—Requirements and tests* **
- 2.32** IEC 60601-2-66, *Medical electrical equipment—Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems* *
- 2.33** IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes—Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications* *

* Certain provisions of this normative reference constitute provisions of this standard, as specified in the text of this standard.

** All provisions of this normative reference constitute provisions of this standard.

- 2.34 IEC 62281:2012, *Safety tests for primary and secondary lithium cells and batteries during transport* *
- 2.35 IEC 62304, *Medical device software—Software life cycle processes* **
- 2.36 IEEE 1413-2010, *IEEE Standard Framework for Reliability Prediction of Hardware* *
- 2.37 ISO 14155, *Clinical investigation of medical devices* *
- 2.38 ISO 14708-1, *Implants for surgery—Active implantable medical devices—Part 1: General requirements for safety, marking and for information to be provided by the manufacturer* *
- 2.39 ISO 14708-7:2013, *Implants for surgery—Active implantable medical devices—Part 7: Particular requirements for cochlear implant systems* *
- 2.40 ISO 14971, *Medical devices—Application of risk management to medical devices* **
- 2.41 ISO 15223-1:2012, *Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied—Part 1: General requirements* *
- 2.42 ISO 8601, *Data elements and interchange formats—Information interchange—Representation of dates and times* *
- 2.43 ISO/TS 10974, *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device* **
- 2.44 MIL-STD-883H, *Department of Defense Test Method Standard: Microcircuits (26 Feb 2010)* *
- 2.45 NIST Special Publication 330, *The International System of Units (SI). (Taylor BN and Thompson A, authors), Gaithersburg (MD): National Institute of Standards and Technology, 2008.* *
- 2.46 NIST Special Publication 811, *Guide for the Use of the International System of Units (SI). (Taylor BN and Thompson A., authors), Gaithersburg (MD): National Institute of Standards and Technology, 2008.* *

3 Definitions

For the purposes of this standard, the following definitions apply.

- 3.1 **accessories:** Components which are supportive of the function and/or application of the medical device system, but which are not essential to its operation during the device's intended medical application.
- 3.2 **accompanying document:** Document accompanying a medical device and containing information for those accountable for the installation, use, and maintenance of the medical device, the operator, or the user, particularly regarding safety.

IEC 60601-1:2005

* Certain provisions of this normative reference constitute provisions of this standard, as specified in the text of this standard.

** All provisions of this normative reference constitute provisions of this standard.

- 3.3 active implantable medical device:** Active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain in place after the procedure.

NOTE—For purposes of this part of ISO 14708, an active implantable medical device may be a single active medical device, or a system consisting of a set of components and accessories which interact to achieve the performance intended by the manufacturer. Not all of these components or accessories may be required to be partially or totally implanted, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

ISO 14708-1:2014

- 3.4 active medical device:** Medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

ISO 14708-1:2014

- 3.5 auditory brainstem implant system:** Active implantable medical device, comprising implantable and non-implantable parts, intended to treat hearing impairment via electrical stimulation of the auditory brainstem.

NOTE—Most currently non-implantable parts could in the future become implantable parts.

ISO 14708-7:2013

- 3.6 bench test:** Evaluation of device performance under simulated use conditions.

- 3.7 bilateral stimulation:** Stimulation in which there is intended representation of sound information by electrical stimulation to both sides of the auditory system in a coordinated manner.

- 3.8 biphasic pulse:** Pulse that has both negative and positive going phases.

ISO 14708-7:2013

- 3.9 body-worn part:** Non-implantable part of the implant system worn on the body (e.g., belt or ear level).

ISO 14708-7:2013

- 3.10 catheter:** Flexible tube allowing access to a point within the body at its distal end through a lumen, often for delivering a substance.

NOTE—A catheter may be combined with a lead.

ISO 14708-1:2014

- 3.11 censoring:** Terminating a test after either a given duration or a given number of failures.

NOTE—A test terminated when there are still unfailed items may be called a “censored test,” and test time data from such tests may be referred to as “censored data.”

IEC 61649:2008

- 3.12 charge density:** The amount of charge per phase expressed per geometric area of an electrode contact.

- 3.13 cochlear implant system:** Active implantable medical device, comprising implantable and non-implantable parts, intended to treat hearing impairment via electrical stimulation of the cochlea.

ISO 14708-7:2013

- 3.14 component:** In the context of reliability prediction and reporting, a saleable device that the recipient uses.
- 3.15 cumulative failure percentage:** The cumulative failure probability expressed as a percentage.
- 3.16 cumulative failure probability:** The estimated probability of a unit being explanted from the time of implant to the end of a given interval.
- 3.17 cumulative removal percentage:** The preferred term to be used in public reliability reporting when referring to the cumulative failure percentage.
- 3.18 cumulative survival probability:** The estimated probability of a unit not being explanted from the time of implant to the end of a given interval.
- 3.19 device failure:** Condition in which a device no longer performs the function for which it was intended.

This definition includes failure for medical reasons and failure for unknown reasons, which are treated as subcategories of failure. This definition eliminates the need for the often used, but ambiguous, term “soft failure.”

Devices that are functioning in such a manner as to provide potential medical benefits to the patient are considered to be in service.

NOTE 1—Battmer et al. (2010) defines device failure as an out of specification condition that leads to device explant or to “no or reduced” clinical benefit (for devices still implanted); see Figure 1 in Battmer et al. (2010).

NOTE 2—This term can apply to a device that could be out of specification (ISO 5841-2:2014).

- 3.20 distal:** Located away from the point of attachment to the stimulator.

ISO 14708-7:2013

- 3.21 electrical open:** Condition in which there is a breakage or disconnection within an electrical circuit path, preventing the passage of current.
- 3.22 electrical short:** Condition in which there is a connection between two or more electrical circuit paths, which causes unintended passage of current.
- 3.23 electrode array:** Distal part of a lead containing more than one electrode contact.

ISO 14708-7:2013

- 3.24 electrode array malfunction:** A condition where the electrode array fails to meet the manufacturer's specification.
- 3.25 electrode contact:** Electrically conducting part designed to form an interface with body tissue or body fluid.

ISO 14708-7:2013

- 3.26 electrode impedance:** Resistance measured between the electrode output and ground.
- 3.27 electronic failure:** Condition where the electronic components or circuit fail to perform the expected function as defined in the manufacturer's specification.
- 3.28 explantation:** Surgical removal of an implanted device.
- 3.29 failed component return rate:** Percentage of the total number of original non-implantable components sold which are returned as failed devices each month. (See Section 11.4.3.2.)

3.30 failure: State or condition of not meeting a predetermined objective.

NOTE—"Failure" is not sufficiently specific to express the significance of a change in performance. In addition, "failure" implies a negative connotation for pulse generators that meet all longevity claims and cease functioning due to normal power-source depletion.

ISO 5841-2:2014

3.31 failure due to internal moisture: Failure due to a moisture level greater than that specified in Section 20.7.

3.32 failure mechanism: Physical, chemical, thermodynamic, medical, or other process that results in failure.

3.33 failure mode: Effect by which a failure is observed.

3.34 failure site: Location of the failure within and/or relative to the implant.

3.35 fault-free: Condition of returned external devices that are found to be in specification after testing.

NOTE—Such a device might have cosmetic and other damage because of normal wear and tear that does not affect the functioning device

3.36 firmware component: Machine code that is stored in the memory of a medical device and is executed by the medical device to perform an intended function.

3.37 hand-held equipment: Equipment intended to be supported by the hand during normal use.

ISO 14708-1:2014

3.38 hardware component: Physical components, including mechanical and electronic parts, that together form the medical device.

3.39 harm: Physical injury or damage to the health of people, or damage to property or the environment.

ISO/IEC Guide 51:2014

3.40 hazard: Potential source of harm.

ISO/IEC Guide 51:2014

3.41 hazard control: Design feature of an active implantable medical device intended to ensure that it does not cause an unacceptable hazard.

ISO 14708-1:2014

3.42 hearing assistive technology: Devices that are designed to aid in certain listening situations (e.g., telephone, television, theater, classroom, restaurant, etc.). These devices are intended to improve the signal to noise ratio by delivering the signal directly to the cochlear implant and overcoming the effects of distance. Types of HAT include induction loop, frequency modulated, digitally modulated, radio, and infrared systems.

3.43 hermeticity: Ability of an implant to resist the ingress of moisture into the internal cavity.

3.44 impact failure: Condition where an implant fails to perform its intended function because of a physical impact.

3.45 implant system: Either a cochlear implant system or an auditory brainstem implant system.

ISO 14708-7:2013

3.46 in service: Functioning in such a manner as to provide potential medical benefits to the patient.

NOTE—A device thus described is not necessarily in specification (see definitions for **in specification** and **out of specification**).

ISO 5841-2:2014

3.47 in specification: Having characteristics within the limits recommended by the manufacturer for clinical use.

NOTE—A device thus described is not necessarily in service (see definitions for **in service** and **out of service**) or explanted.

ISO 5841-2:2014

3.48 intended use: Use for which a product, process, or service is intended, according to the specifications, instructions, and information provided by the manufacturer.

ISO 14971:2007

3.49 label: Area bearing a marking, affixed to a device or package but not an integral part of the device or package.

ISO 14708-1:2014

3.50 lead: Flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length.

ISO 14708-1:2014

3.51 life cycle: All phases in the life of a medical device, from the initial conception to final decommissioning and disposal.

ISO 14971:2007

3.52 life test: Test conducted to estimate or verify the durability of a product.

IEC 61649:2008

3.53 load: Application or environmental condition needed (electrical, thermal, mechanical, chemical) to precipitate a failure mechanism.

3.54 magnet: Component producing an external magnetic flux.

ISO 14708-7:2013

3.55 manufacturer's specification: Defined attributes of the product when all manufacturing process steps are completed and all tests indicate that the defined characteristics of the product are within the nominal acceptance window.

3.56 marking: Inscription on a device, package, or label.

ISO 14708-1:2014

3.57 medical device: Article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury; investigation, replacement or modification of the anatomy or of a physiological process.

ISO 14708-1:2014

- 3.58 medical reasons:** Reasons unrelated to the device or its operation (e.g., infection, extrusion).

ISO 5841-2:2014

- 3.59 medicinal substance:** Substance which, when used separately, is intended for the treatment or prevention of disease in human beings, or which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

ISO 14708-1:2014

- 3.60 model designation:** Name and/or a combination of letters and numbers used by a manufacturer to distinguish, by function or type, one device from another.

ISO 14708-7:2013

- 3.61 moisture:** Presence of water in either a gaseous or liquid phase.

- 3.62 no fault found (NFF):** Designation of an explanted returned device categorized as a medical failure that underwent complete failure analysis testing and is fully functional.

- 3.63 non-implantable part:** External part of the implant system.

ISO 14708-7:2013

- 3.64 non-reusable pack:** Single-use pack designed to allow the contents to be sterilized and to maintain that sterility.

ISO 14708-1:2014

- 3.65 operating time:** Time interval for which the item is in an operating state.

IEC 61649:2008

- 3.66 out of service:** Not providing a medical benefit to the patient.

NOTE—A device thus described is not necessarily out of specification (see definition of **out of specification**) or explanted.

ISO 5841-2:2014

- 3.67 out of specification:** Having one or more characteristics outside the limits established by the manufacturer for clinical use.

NOTE—A device thus described is not necessarily out of service (see definitions of **out of service** and **in service**).

ISO 5841-2:2014

- 3.68 output signal:** electrical output, either pulsatile or analogue, of an implant system intended to stimulate the auditory pathways.

ISO 14708-7:2013

- 3.69 packaging system:** Combination of the sterile barrier system and protective packaging.

ANSI/AAMI/ISO 11607-1:2006

- 3.70 population sample:** Group of devices designated for the purpose of reporting performance experience that is assumed to be representative of the population.
- ISO 5841-2:2014
- 3.71 portable equipment:** Equipment intended to be moved from one location to another while being used or between periods of use while being carried by one or more persons.
- ISO 14708-1:2014
- 3.72 predicted reliability:** For the stated conditions of use, and taking into account the design of an item, the reliability computed from the observed, assessed, or extrapolated reliabilities of its parts, interconnects, and interfaces.
- IEEE 1413:2010
- 3.73 primary failure mechanism:** Root cause of a failure that if it had not occurred the device would not have been explanted (for implantable devices) or returned by the patient (for non-implantable devices).
- 3.74 process:** Set of interrelated or interacting activities which transforms inputs into outputs.
- ISO 9000:2015
- 3.75 protective packaging:** Configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use.
- ANSI/AAMI/ISO 11607-1:2006
- 3.76 proximal:** Located closest to the point of attachment to the stimulator.
- ISO 14708-7:2013
- 3.77 pulse:** Specified electrical output signal (voltage or current) of a specified amplitude and duration.
- ISO 14708-7:2013
- 3.78 receiver-stimulator:** Implantable part of the implant system containing electronic circuitry required to produce electrical stimulation.
- NOTE—Most currently non-implantable parts could in the future become implantable parts.
- 3.79 record:** Document stating results achieved or providing evidence of activities performed.
- ISO 9000:2015
- 3.80 reference electrode:** Electrically conducting part designed as a return path for electrical stimulation current.
- ISO 14708-7:2013
- 3.81 registered explant:** Registered implant for which the date of explantation is known by the reporting party.
- ISO 5841-2:2014
- 3.82 registered implant:** Implanted device for which the date of implantation is known by the reporting party.
- ISO 5841-2:2014

- 3.83 reliability:** Ability of a product to function and meet specified performance, for a specified period of time, under the life cycle application conditions.
- 3.84 reliability test:** Experiment carried out in order to measure, quantify, or classify a reliability measure or property of an item.
- IEC 61649:2008
- 3.85 reporting party:** Individual or organization publishing clinical cochlear implant system data or the analysis thereof.
- ISO 5841-2:2014
- 3.86 returned device:** A medical device that has been in use in the field by a patient or clinician and is returned to the manufacturer because it does not perform its intended function.
- 3.87 revision surgery:** Any surgical intervention required without the removal of the device. This does not include known surgical procedures required by approved labeling.
- 3.88 risk:** Combination of the severity of a harm and the likelihood of that harm occurring.
- 3.89 risk-based:** Characteristic of a process that uses the risk assessment to determine a course of action.
- 3.90 sales packaging:** Packaging that protects and identifies the active implantable medical device during storage and handling by the purchaser.
- NOTE—The sales packaging may be enclosed in further packaging (e.g., a “shipping package”) for delivery.
- ISO 14708-1:2014
- 3.91 sample size:** Number of devices required to provide data that meets a required statistical level of confidence for a given statistical analysis method.
- 3.92 serial number:** Unique combination of letters and/or numbers, selected by the manufacturer, intended to distinguish a device from other devices with the same model designation.
- ISO 14708-7:2013
- 3.93 shipping package:** Packaging that protects the sales packaging during shipping from the manufacturer.
- 3.94 sound-processing strategy:** Algorithm by which the device processes sound information to create electrical and/or acoustic stimulation delivered during the device’s intended medical application.
- 3.95 sound processor:** Non-implantable component of a cochlear implant system that is capable of receiving acoustic information from an external source, modifying it, and transmitting this information via either a radio-frequency link or a transcutaneous plug to the receiver/stimulator of an implant.
- 3.96 sterile barrier system:** Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.
- ANSI/AAMI/ISO 11607-1:2006
- 3.97 sterile pack:** Non-reusable pack in which the contents have been sterilized.
- NOTE—The sterile pack is typically stored in inventory and delivered to the operating room within the sales packaging.
- ISO 14708-1:2014

- 3.98 stress:** Intensity of applied environmental load.
- 3.99 subsystem:** In the context of reliability prediction and reporting, a subset of the cochlear implant system, e.g., the implantable subsystem, the externals subsystem, the programming subsystem.
- 3.100 system:** Set of interrelated or interacting elements. In the context of reliability prediction and reporting, a system is a collection of components that are grouped together and have a similar expected reliability.
- IEC 60300-1:2014
- 3.101 time-to-failure:** Operating time accumulated from the implantation date to explantation date or date of decision to explant as confirmed by healthcare provider if explant date is unavailable.
- 3.102 type test:** Test performed on a representative sample of a system or component with the objective of determining if the tested unit, as designed and manufactured, can meet the requirements of this standard. Type tests are commonly used in the verification and validation of engineered products and apply to hardware and software components and/or systems or subsystems incorporating either or both.
- 3.103 use-before date:** Date after which the manufacturer recommends that the implant system should not be implanted.
- ISO 14708-7:2013
- 3.104 user accessories:** Set of physical devices that can be used with a medical device to perform certain functions.

4 Units, abbreviations, and symbols

Units shall conform to the International System of Units (SI) (see NIST Special Publications 330 and 811), unless otherwise stated. When appropriate, symbols, abbreviated terms, and identification color may be used in the markings and accompanying documents of a cochlear implant system. Symbols, abbreviated terms, and identification color shall conform to published international standards and conventions (e.g., ISO 15223-1), unless specifically excluded for use by the Food and Drug Administration (FDA) (see Section 14.2.15). If no standard exists, the symbols, abbreviated terms, and identification color shall be described in the accompanying documentation.

The manufacturer shall demonstrate compliance with this section.

NOTE—This requirement does not preclude the use of symbols defined in other standards or special symbols defined in the accompanying documentation.

The units, abbreviations, and symbols used in this standard are as follows:

4.1 Units

A	ampere
Ah	ampere hour
C	coulomb
dBA	acoustic decibel (A-scale frequency weighting)
g	gram
g-force	acceleration caused by gravity at Earth's surface; defined as 9.80665 m/s ² (SI unit not used in vibration testing)
h	hour
Hz	hertz
J	joule

L	liter
m	meter
min	minute
Pa	pascal
s	second
V	volt

4.2 Abbreviations

A/D	analog-to-digital
ADC	analog-to-digital conversion
ASIC	application specific integrated circuit
BPF	band-pass filter
C	battery Ah capacity at full charge
CDC	Centers for Disease Control and Prevention
CI	cochlear implant
CRP	cumulative removal percentage
DMM	digital multimeter
DUT	device under test
EABR	electrical auditory brainstem response
EAS	electronic article surveillance
ECAP	evoked compound action potential
EI	electrode
eSRT	electrical stapedial reflex threshold
ESD	electrostatic discharge
FM	frequency modulation
HAT	hearing assistive technology
HW	hardware
LPF	low-pass filter
MR	magnetic resonance
MRI	magnetic resonance imaging
N/A	not applicable
PCB	printed circuit board
rect	rectification
RCL	resistor – capacitor - inductor
rms	root mean square
SW	software
T	threshold level

4.3 Symbols

(none)

5 General requirements for characterizing a cochlear implant system

The descriptions contained in this section are based on the principles and methodologies of currently approved cochlear implants and do not limit the manufacturer's description or design of the current device. Additional device descriptions shall be provided as applicable to reflect the system design.

NOTE—This section defines the minimal requirements for technical information necessary for characterization of a cochlear implant system for regulatory review. Consistent with Section 0, the information required in this section is confidential to the manufacturer unless stated otherwise.

5.1 General description of device, intended uses, and model designations

The documentation created for regulatory review purposes shall include a general description of the device, its various configurations for intended medical applications, and the corresponding model designations.

A block diagram of device system components and connections/links during the patient use and clinical programming scenarios shall be provided. Any off-the-shelf or consumer components shall be specified (e.g., Windows personal computer (PC)/platform running clinical mapping software). All possible wired connections and wireless links shall be identified, including optional connections/links which should be designated as such. Forward and backward links shall be specified and indicated separately as applicable, including forward telemetry between sound processor and implant during patient use, and back telemetry during clinical fitting for impedance measurements or measuring electrically evoked compound action potentials. Any mains powered connections (optional for laptop or required) should be specified. An example diagram is shown in Figure 1.

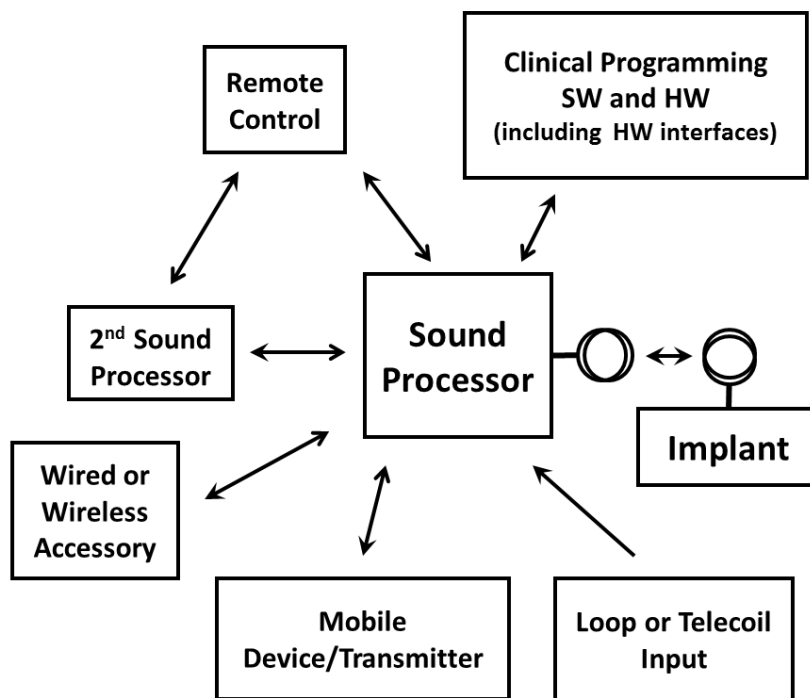


Figure 1—Example block diagram of device system hardware and software components and connections/links

5.2 Specific inventory of system components

5.2.1 Implantable components

5.2.1.1 Receiver–stimulators

The documentation shall list receiver–stimulators that are components of the device system and describe their functions.

The manufacturer shall demonstrate compliance to this section.

5.2.1.2 Electrode systems

The documentation shall list the electrode arrays and return electrodes that are components of the device system and shall describe their function. The detailed information to be provided about electrodes is specified in Section 5.7.

The manufacturer shall demonstrate compliance to this section.

5.2.1.3 Connector systems

5.2.1.3.1 Percutaneous connectors

If the cochlear implant system includes a percutaneous connector system for connection between implantable and non-implantable components, the connector system shall be listed in the documentation and its function described.

The manufacturer shall demonstrate compliance to this section.

5.2.1.3.2 Implantable system connectors

If the cochlear implant system includes a system for connection between implantable components, the connector system shall be listed in the documentation and its function described.

The manufacturer shall demonstrate compliance to this section.

5.2.2 Non-implantable components

5.2.2.1 Sound processors and body-worn accessories

The documentation shall list the sound processors and body-worn accessories that are components of the device system and shall describe their functions.

The manufacturer shall demonstrate compliance to this section.

NOTE 1—Sound processors to be included in the inventory are those used with the cochlear implant system in conventional (purely electrical) and combined acoustic and electrical stimulation. In basic operation, sound processors receive and process sound signals while being battery-powered and transmit processed signals and energy to the implant. Headpiece coils are considered to be an integral part of the sound processor and are included as specific items in the inventory listing. If the sound processor communicates with an acoustic hearing instrument as part of its function, the hearing instrument is included in the inventory. The information to be provided about cables connecting the headpiece coil to the sound processor is specified in Section 5.2.2.3.

NOTE 2—Body-worn accessories are ancillary devices that might be used with sound processors in order to extend the processors' basic operation or body-worn configuration. Examples are battery packs, FM systems that connect to the sound processors, accessory microphones, and remote controls. The information to be provided about accessory cables that either interconnect the body-worn accessories with the sound processor or connect signals to the accessory or auxiliary connectors of sound processors is specified in Section 5.2.2.3.

5.2.2.2 Non-body-worn accessories and replaceable body-worn components

The documentation shall list the user accessories that might be required with the device and shall describe their functions. Examples of user accessories include battery chargers, remote controls, carrying cases, and belt clips. Items that are considered to be user-replaceable items (i.e., consumables) should also be listed. Examples of user-replaceable items include batteries, magnets, and microphone covers. The information to be provided about cables is specified in Section 5.2.2.3.

The manufacturer shall demonstrate compliance to this section.

5.2.2.3 Body-worn and non-body-worn cables

The documentation shall list the user cables that might be required with the device and shall describe their functions. Cables with similar function and varying only in length shall be listed according to their function, and the available lengths shall be described.

The manufacturer shall demonstrate compliance to this section.

5.2.2.4 Components for system clinical support (e.g., clinical programming pods, clinical mapping software, test materials)

The documentation shall list the hardware and software components that might be required for device programming, training, testing, diagnostics and other clinical activities, and their functions shall be described. See section 5.8 for details on features of clinical software.

The manufacturer shall demonstrate compliance to this section.

5.2.2.5 Components for surgical support (e.g., insertion tools, templates)

The documentation shall list the components of the system intended to support surgical insertion, removal, and/or retention of the implantable device, and their functions shall be described.

Manufacturer shall demonstrate compliance to this section.

5.2.3 Compatible components

A table describing compatibility of components and features shall be provided. Components and features shall include, but not be limited to, implantable components, sound processors, sound processing strategies, front-end signal processing features, and accessories.

Manufacturer shall demonstrate compliance to this section.

5.3 Wireless technology description

The documentation shall include a description of the system's wireless operation including a list of the system components which include wireless functionality. A description for each device with a wireless interface shall be included. A near-field inductive link between an externally worn sound processor and implanted receiver-stimulator is considered part of the system functionality and therefore should be sufficiently described. All wireless links shall be identified in the system component block diagram (see Figure 1 for an example), and the description for each wireless link shall include the following:

- a) Device function
- b) Wireless claims
- c) Radio-frequency
- d) Modulation scheme
- e) Data rate
- f) Bandwidth
- g) Output power
- h) Specific absorption rate (SAR) (if applicable)

- i) Range of operation
- j) Security protection
- k) Provisions for data integrity
- l) Wireless coexistence
- m) Wireless quality of service

The manufacturer shall describe the following:

- a) The wireless interfaces providing input signals (their purpose; whether they are bidirectional or unidirectional; the frequency and modulation scheme; the indoor range in actual use, depicted as a polar diagram; and applicable standards)
- b) The RF link to the implant (the skin flap range, the compatible implants, and the sound processors)

The manufacturer shall demonstrate compliance to this section.

5.4 System hardware description

The manufacturer shall create a narrative description and general block diagram of the hardware components of the CI device system configurations described in Section 5.1. The block diagram shall depict all relevant hardware components required to support the medical applications of the device. This description shall include the entirety of the system, including non-implantable and implantable components. An example of a general block diagram of cochlear implant system is shown in Figure 1. The submitted block diagram shall be tailored to the details of the specific system submitted for regulatory review.

In addition multiple block or sub diagrams that sufficiently describe the hardware system shall be provided. It is up to the manufacturer to depict the firmware components as either hardware or software so as to maximize the clarity of the overall system description.

At least the following elements shall be included in the description and diagram(s): acoustic signal transduction by microphone(s); auxiliary signal sources; analog-to-digital (A/D) conversion and signal pre-processing by sound processor; hardware components required to implement signal processing strategies; digital-to-analog (D/A) conversion, modulation of radio-frequency (RF) carrier signal and transmission via the transmission coil; pickup of transmitted signal by implant coil; demodulation and digitization by implant circuitry; generation of waveforms for electrical stimulation; passing signals through direct-current (DC) blocking capacitor(s) or other methods to ensure zero net charge delivery; and delivery of electrical current signals to various electrodes in the electrode array.

Methods of powering both non-implantable and implantable subsystems shall be included in the description.

The specific description of the stimulation array is addressed in Section 5.7.

The manufacturer shall demonstrate compliance to this section.

5.5 System software, including sound processing strategies

The manufacturer shall provide a narrative description of the required software elements of the system for the patient-use scenario. Based on technology available at the time of the publication of this standard, software/firmware typically resides on the sound processor but not on the implant, but this configuration does not limit future designs. Three accompanying diagrams shall be provided to accompany the narrative:

- a) A high-level overview diagram (block diagram) that illustrates the major software elements and their inputs and outputs and depicts major hardware elements, such as digital signal processor(s) [DSP(s)] and microcontroller(s),
- b) A hierarchical breakdown of system software architecture, and
- c) A detailed end-to-end signal-path-overview block diagram showing the major processing blocks from microphone transduction (and auxiliary inputs) to generation and delivery of the coil-drive signal to the transmission coil

An example diagram of a high-level overview diagram (item a) above) is shown in Figure 2. This diagram of an early generation, single-channel cochlear implant device illustrates at a high level the inputs/outputs and the key signal processing elements in their relation to the hardware components of the system. A high-level diagram of a modern

cochlear implant system would convey a similar level of functional information, while showing the greater complexity and functionality of the present system.

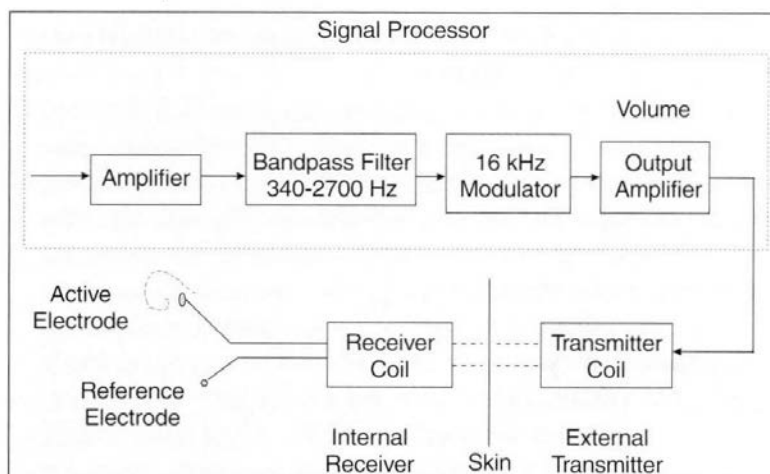


Figure 2—High-level overview block diagram of a simple cochlear implant system

[Reprinted with permission from Loizou PC. Mimicking the human ear. *IEEE Signal Processing Magazine*, Sept 1998, pp 101-130.]

An example diagram of hierarchical breakdown of system software architecture (item b in 4.5) is shown in Figure 3. In this example, system software is broken into the three high-level system areas of DSP, microcontroller, and read-only memory (ROM). Additional or alternate subsystem blocks and/or software units shall be included as appropriate.

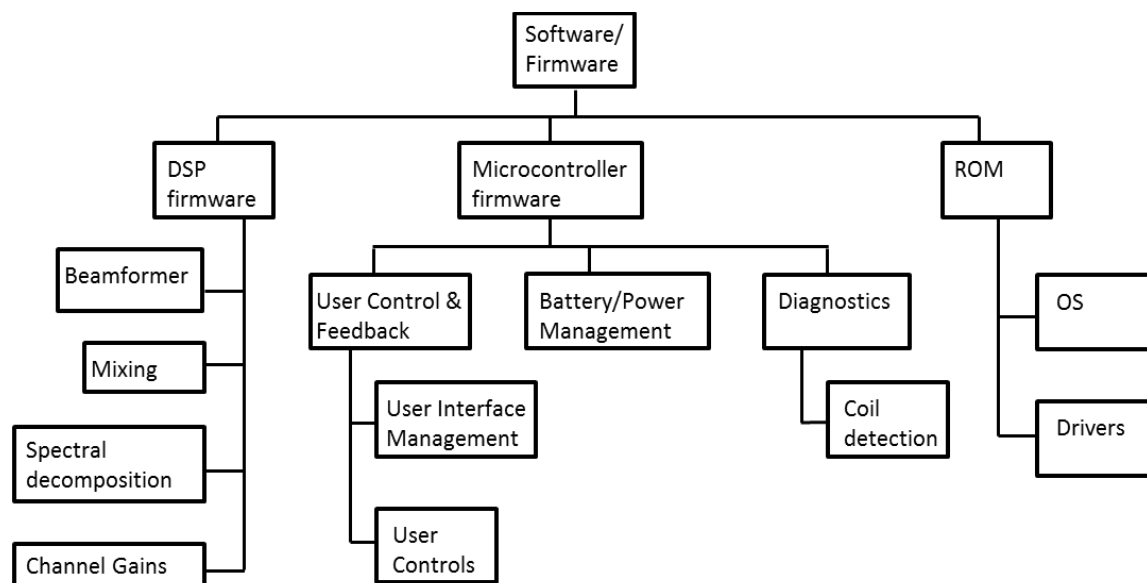


Figure 3—Example of a system software architecture diagram for a sound processor

An example diagram of a detailed end-to-end signal-path overview block diagram (item c) in 4.5) is shown in Figure 4.

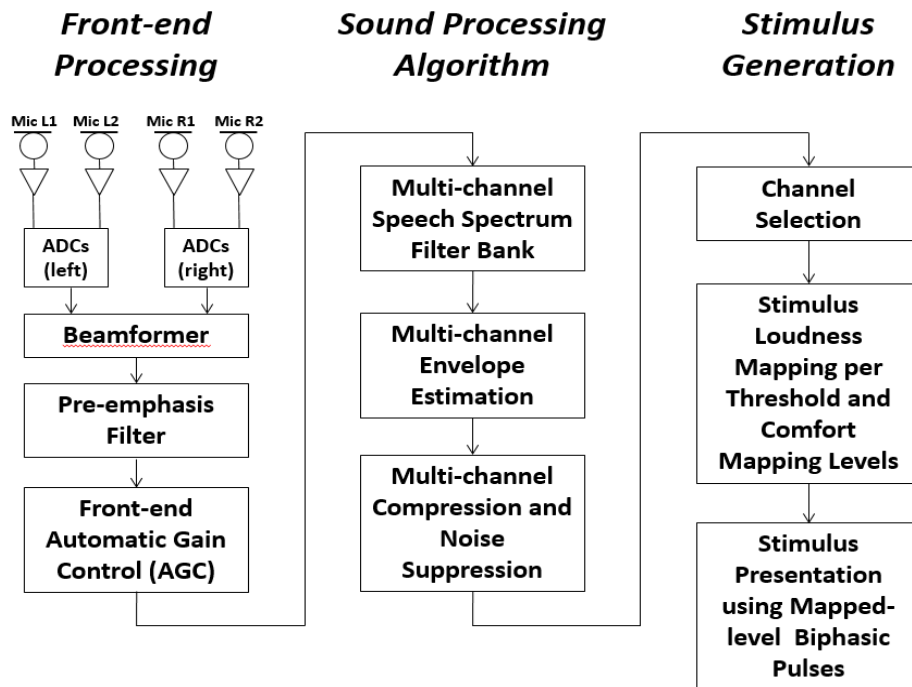


Figure 4—Diagram of a detailed end-to-end signal-path overview block diagram

The manufacturer shall also create a narrative description and general block diagram of the sound-processing strategies and their software implementations on the hardware components of the CI device system configurations. The block diagram shall depict all relevant processing components required to support the medical applications of the device.

The block diagrams of the system or sound processing shall include multiple subdiagrams sufficient to describe the software system. It is up to the manufacturer to depict the firmware components as either hardware or software so as to maximize the clarity of the overall system description.

For each proposed sound-processing strategy, a narrative description and block diagram(s) shall be provided that specify in detail the decomposition of the audio signal into individual frequency bands and the associated frequency-band-dependent signal processing (see Figure 5 for an example). The narrative description shall clearly state the design principles of the sound-processing strategy and shall describe the processing of signals based on the block diagram. Special considerations for modes of operation using bimodal and/or bilateral stimulation shall be included.

Plots of representative signals from the various processing stages shall be depicted within the block diagrams or presented separately and referenced to the block diagram. These plots shall be provided for a representative sample of audio signals, such as speech utterances, which illustrate the intended design principles of the sound-processing strategy and overall system (see Figure 5 for an example).

The manufacturer shall demonstrate compliance to this section.

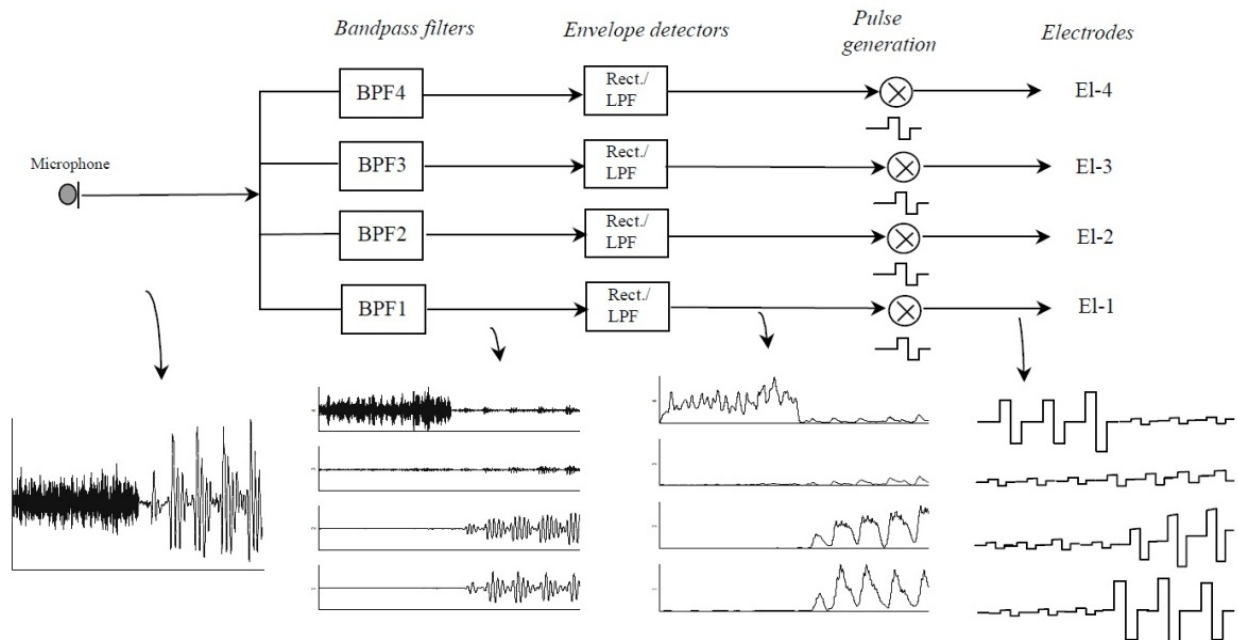


Figure 5—Example of a block diagram of the continuous interleaved sampling (CIS) sound coding strategy (reprinted with permission from Loizou PC (1998) Mimicking the Human Ear in IEEE Signal Processing Magazine Sept, pp 101-130)

The signal processing stages depicted in the block diagrams shall be appropriately specified and defined. The following information shall be included, as appropriate (but is not limited to):

- a) Front-end signal processing and (audio signal) A/D converter specifications, such as the following:
 - i. Microphone characteristics, including the following:
 - Number and mechanical configuration of microphones
 - Dynamic range and noise floor of the microphone(s)
 - Frequency response characteristics
 - Directionality characteristics and processing implementation
 - ii. Preamplifier gain and frequency response characteristics
 - iii. Provisions for microphone testing, if available
 - iv. Specification of alternative input signals
 - Auxiliary signal input types
 - Direct connect standard implementation (in accordance with IEC 60118-0)
 - FM signal sources
 - Telecoil features (in accordance with IEC 60118-0)
- b) Other methods of signal input, including digital streaming
- c) A/D converter specifications, including the following:
 - i. Resolution of converter (e.g., 8 bit)
 - ii. Sampling rate in samples per second
 - iii. Provisions for preventing signal aliasing
- d) Listing and definitions of pre-emphasis or pre-processing operations that occur prior to band-pass filtering (which might occur before or after the audio signal A/D conversion). See Figure 6, including the following:
 - i. Spatial audio selectivity processing, such as beam forming
 - ii. Signal windowing with definitions of window type (e.g., Hanning, Hamming), window duration, and other window characteristics
 - iii. Automatic gain control (AGC), if appropriate
 - iv. Volume control (VOL), if appropriate
 - v. Sensitivity control (SENS), if appropriate
 - vi. Definition of input dynamic range (IDR), if appropriate

- e) Functional specifications and implementation details for volume and sensitivity controls, as appropriate, including remote control features.
- f) Other pre-processing, including speech enhancement, sound classification, and/or noise reduction strategies
- g) Spectral decomposition and related signal processing operations for each approved sound processing strategy, such as the following:
 - i. The operations and specifications for spectrally decomposing the audio signal into individual frequency bands, e.g., by means of the following:
 - A bank of band-pass filters, each with a different center frequency (as in Figure 5)
 - The Fast Fourier Transform (FFT), with definition of the FFT length
 - The Wavelet transform
 - ii. The number of individual frequency bands (e.g., the number of band-pass filters and/or the number of groupings of successive FFT bins for FFT based spectral decomposition)
 - iii. The sharpness of frequency tuning of individual frequency bands (e.g., the quality factor [Q factor] of band-pass filters and/or the number of successive FFT bins that are grouped into one frequency band)
 - iv. Definition of the computation and extraction of envelope and/or fine-structure information from individual frequency bands, e.g.:
 - If envelope information is extracted by means of low-pass filtering, LPF cutoff frequencies and any other influential parameters shall be defined.
 - If the Hilbert transform is used, all relevant operations and parameters shall be defined and illustrated.
 - v. Definition of the mapping function(s) for converting the frequency-band envelope and/or fine-structure information into patterns of electrical current delivered to individual electrodes (e.g., definition of the compression function). An illustration similar to those shown in Figure 6 should be included in the description.

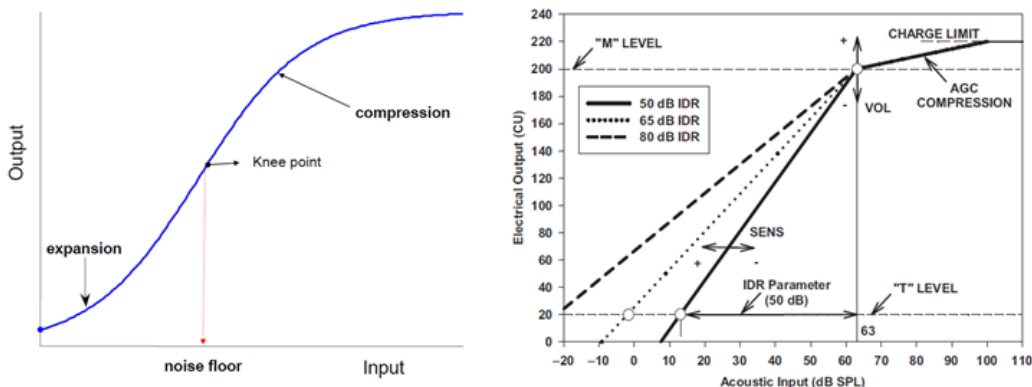


Figure 6—Examples of various mapping functions

[Reprinted with permission from Loizou P. Møller AR (ed): Cochlear and Brainstem Implants. Adv Otorhinolaryngol. Basel, Karger, 2006, vol 64, pp 109-143 (left)]

[Reprinted with permission from Holden LK, Reeder RM, Firszt JB and Finley CC. Optimizing the perception of soft speech and speech in noise with the Advanced Bionics cochlear implant system. *Int J Audiol*, 50:255–269, 2011 (right).]

5.6 Physical specifications of sound processing hardware

The features of the sound processor (as described in Section 5.2.2.1) shall be provided in the documentation. Examples include, but are not limited to, weight, dimensions, IP rating, and the composition of materials in contact with skin.

The manufacturer shall describe the following:

- a) The size of the device: length x width x height (in millimeters [mm])
- b) The weight of the device, including batteries (in grams)
- c) Whether the battery is rechargeable or single-use
- d) The battery chemistry type

The manufacturer shall demonstrate compliance to this section.

5.7 Electrode specification and characteristics

The documentation shall include the following information regarding the specification for and characteristics of the electrode system, including leads, electrode arrays, and reference electrodes, as applicable:

- a) The possible electrical stimulation modes (e.g., monopolar, bipolar, multipolar). For multipolar, list details such as the number of electrically-independent electrode contacts and the number of electrically-dependent or virtual contacts.
- b) The cross-sectional array shape (e.g., round, square) including the array shape at the cochlear insertion point (e.g., at the round window) and also at the apical tip
- c) The overall shape and degree of curl of the array (e.g., perimodiolar, straight, or intermediate) and information (presence/absence and diameter) about the lumen for a stylet, if applicable
- d) The expected range of insertion angles (in degrees) and the insertion depth (in mm) of the array
- e) A listing of the materials used for the conductors, electrode contacts, reference electrodes, and insulation of the leads
- f) A statement advising whether the lead and/or electrode array contains a medicinal substance as an integral component, giving the identity of the medicinal substance and referencing additional documentation, in accordance with Sections 1 and 12.14
- g) The nominal values of the physical dimensions, including the following:
 - i. The length and diameter of the leads (in mm)
 - ii. The cross-sectional dimensions of the electrode array at the proximal and distal ends (in mm)
 - iii. The dimensions of the electrode contacts at the proximal and distal ends (in mm)
 - iv. The geometric surface area of the smallest and largest stimulating electrode contacts (in mm²)
 - v. The center-to-center distance(s) between electrode contacts and the distance between the most proximal and most distal stimulating electrode contacts (in mm)
 - vi. The dimensions (in mm) and geometric surface area of the reference electrodes (in mm²), if applicable
 - vii. The geometric surface area of the smallest and largest stimulating reference electrodes (in mm²), if applicable
- h) The connector geometry (lengths and diameters in mm), if applicable, or a reference to published connector standards, including any designations or markings
- i) The range of electrode impedances typically occurring during normal operation of the implantable device for its intended use, including a description of the methodology used to measure electrode impedances as part of the normal operation and/or clinical support of the device and compliance with Section 8.2
- j) The methodology of identifying or calculating an electrical short within the electrode array and/or lead
- k) The methodology of identifying or calculating an electrical open within the electrode array and/or lead
- l) The range of charge and charge density of stimulating electrodes during normal operation of the implantable device
- m) The accuracy of the measurement of the waveform voltage at one or more points in response to a biphasic current pulse *in vitro* (0.9% weight/volume [w/v] saline). Measurements should be made using the implant impedance-telemetry system and compared to the voltage waveform measured via oscilloscope. Repeated pulse presentations and averaging are permitted. Measurements should be made on a representative sample of electrode(s) in the array. The manufacturer should explain with the aid of a diagram at which time points on the voltage waveform the telemetry measurement(s) are made.

Engineering drawings may supplement this information, as appropriate, but are not required.

The manufacturer shall demonstrate compliance to this section.

5.8 Features of clinical fitting software

The clinical fitting software shall be summarized in sufficient technical detail and shall include at minimum the following information, as applicable:

- a) Hardware and software (i.e., platform) requirements for the computer(s) running the clinical fitting software. This information shall also be provided for any additional computer(s) that might be used for clinical fitting, as well as any internet and/or wireless connectivity requirements for the computer(s).
- b) Definition of the clinical unit for each sound processing strategy and/or implant device in terms of physical parameters in current (μA), charge (μC), time (μs) including formulae for converting from clinical to physical units and from physical to clinical units. This information shall be included in the publicly available product data sheets (see Section 12.1).
- c) Identification of the upper and lower boundaries of the parameter space in terms of permissible current and charge (physical units), assuming that voltage compliance and all other parameters (e.g., skin flap thickness) are not limiting factors
- d) Listing of every adjustable mapping parameter along with the range (or selectable options) for each parameter. If there are subsets of parameters that co-vary (e.g., selection of a certain sound processing strategy leads to a certain set of stimulation rates), the co-variance shall be denoted accordingly.
- e) Specification of how impedance and evoked compound action potential measurements are taken, in technical detail, including the following:
 - i. The possible stimulation waveforms (e.g., biphasic pulses)
 - ii. The current levels (in μA), pulse widths (in μs) and charge/pulse (in μC)
 - iii. When measurements are taken, such as impedance measurements are initiated immediately after the headpiece is in place and link is established with the implanted device
 - iv. The number of stimulation current pulses presented from which impedance values are derived from the data, and where in the stimulation phase of the pulse are measurements taken,
 - v. The accuracy and resolution of measurements (i.e., impedance and neural responses)
 - vi. The range of possible measurement times the implant can sample the voltage during the stimulus pulse waveform
- f) Definitions of all automatic decisions built into the fitting software for identifying and flagging open or shorted electrodes
- g) Criteria applied in the software and/or processing strategy to determine if an electrode is used (e.g., impedance and compliance voltage criteria)
- h) Definitions of the way electrode data are presented (e.g., color bands for in- and out-of-range impedances;) and the way that voltage compliance limits are indicated
- i) All possible stimulation modes
- j) Default settings (e.g., common ground mode) as well as all of the possible clinically adjustable settings.

The manufacturer shall demonstrate compliance to this section.

5.9 Stimulation methodology and provisions for safe stimulation

5.9.1 Overview

The manufacturer shall provide a narrative description and a block diagram, with supporting figures (as applicable), of the electrical stimulation methodology, electrodes, and electrode coupling configurations employed for the safe operation of the CI device system configurations described in Sections 5.1, 5.2, 5.3, 5.4, 5.5, and 5.6. The figures shall depict all relevant operating modes required to support the medical applications of the device.

Manufacturer shall demonstrate compliance to this section.

5.9.2 Stimulation waveforms

Manufacturer shall describe the stimulation waveforms employed by the system, including characterization of pulse rate and the number of electrodes stimulated.

Manufacturer shall demonstrate compliance to this section.

NOTE—Figure 5 and Figure 14 illustrate graphical representations of the shape and sequencing of electrical stimulation that might be applied by a device. A graphical representation of stimulation applied by the present device would be helpful in the description.

5.9.3 Stimulation circuitry

The manufacturer shall provide a functional description of the circuitry generating the stimulation waveform, including its electrical characterization (e.g., mode(s) of operation, output range of stimulation, specification of current source, compliance voltage, minimum resolution of stimulus parameters).

Manufacturer shall demonstrate compliance to this section.

5.9.4 Provisions for safe stimulation

The manufacturer shall provide a functional description of the features of the stimulation system which ensure the safe stimulation requirements of Section 17 are achieved.

The implant's method of charge recovery for the stimulus electrodes, including capacitive coupling, bleed resistors, voltage sampling, and/or inter-stimulus grounding intervals should be specified. As applicable, provide specification and tolerances of current sources of cathodic and anodic stimulation phases necessary for charge balancing.

For multi-phasic stimulation waveforms for which a single phase is not well defined (see Figure 14 in Section 17.5), the manufacturer shall provide justification for the safety of the stimulation based on quantitative parameters of the stimulus waveform (e.g., electric power delivered by the electrode over a given time). For multipolar stimulation, the total current delivered by all of the electrodes in the electrode array should be analytically characterized and include the sum of the modulus of the currents in all electrodes.

Manufacturer shall demonstrate compliance to this section.

5.10 Interconnection between implantable and non-implantable parts

The manufacturer shall provide a narrative description and general block diagram (if appropriate) of the interconnection between implantable and non-implantable components of the CI device system configurations described in Section 5.2. The description and block diagram shall depict all relevant components in the transmission of power and information between the implantable and non-implantable components required to support the medical applications of the device. General information on operational frequencies and power levels shall be provided.

The block diagram, if included, should include multiple subdiagrams sufficient to describe the software system. It is up to the manufacturer to depict the firmware components as either hardware or software so as to maximize clarity of the overall system description.

Manufacturer shall demonstrate compliance to this section.

5.11 Ancillary functions of the cochlear implant system

The manufacturer shall provide a narrative description and block diagram, with supporting figures, of the ancillary functions of the cochlear implant system, including, but not limited to, measurement of electrode impedances and recording of field potentials and/or biopotential signals from implanted electrodes. For measurement of electrode impedance and waveform recovery by back telemetry, include specification of the voltage resolution of the analog to digital converter, the test stimulation current and its duration, and any amplification gains.

Manufacturer shall demonstrate compliance to this section.

5.12 Microphones for sound processor

5.12.1 Description of the microphones

The manufacturer shall describe the following:

- a) The number of microphones, their positions, and the spacing between microphones
- b) The directivity of each microphone as a polar diagram
- c) The spectral range of the microphone in the use application
- d) The sensitivity reported graphically or in tabular form as a function of the spectral range of the microphone in the use application
- e) The noise floor reported graphically or in tabular form as a function of the spectral range of the microphone in the use application
- f) The dynamic range reported graphically or in tabular form as a function of the spectral range of the microphone in the use application
- g) The recommended maintenance (e.g., the interval for cleaning of microphone ports or changing of protective covers)
- h) The recommendations and methodologies for field testing of microphones in the clinical environment

Manufacturer shall demonstrate compliance to this section.

5.13 Auxiliary inputs to sound processor

5.13.1 General information

The manufacturer shall describe the following:

- a) The purpose of the auxiliary inputs
- b) The connector type, dimensions, and pin-out
- c) The signal type (e.g., analog, digital)
- d) The levels, sensitivity, and impedances
- e) The out-of-band signaling methods (secondary coding methods not using the primary acoustic microphone signal channel) or any other methods for processing the output of the acoustic microphone signal
- f) The applicable standards
- g) For proprietary interfaces, the compatible components

Manufacturer shall demonstrate compliance to this section.

5.13.2 Inductive links

The manufacturer shall describe the following:

- a) The presence or absence of an inductive link for audio input
- b) The modes supported (e.g., mobile phone, public switched telephone network [PSTN] phone, room loop)
- c) The compliance with IEC 60118-0, as applicable

Manufacturer shall demonstrate compliance to this section.

5.13.3 Hearing assistive technology (HAT), including FM links and other technologies

The manufacturer shall describe the following:

- a) Whether the HAT is integrated or discrete
- b) The frequency of operation and the modulation scheme
- c) The range when used indoors
- d) The features supported
- e) The compatible third-party components

Manufacturer shall demonstrate compliance to this section.

5.13.4 Direct connection features

The manufacturer shall describe the following:

- a) The purpose(s) of the direct connection features (e.g., clinical programming, firmware upgrade, diagnostics, audio input/output)
- b) The out-of-band signaling (i.e., secondary coding methods such as impedance signaling)
- c) The compatible systems and software

Manufacturer shall demonstrate compliance to this section.

5.14 Remote controls

5.14.1 Description of the remote control

The manufacturer shall describe the following:

- a) The number of implant systems that can be controlled
- b) The type of controls (e.g., keypad, buttons, touchscreen) and their functionality (e.g., the parameters that can be changed on the sound processor)
- c) The type of indicators (e.g., LED, display) and information provided
- d) Whether the remote control has a key lock and, if applicable, a description of the key lock

Manufacturer shall demonstrate compliance to this section.

5.14.2 Electrical properties

The manufacturer shall describe the following:

- a) The communication technology (e.g., infrared, ultrasound, electromagnetic)
- b) The data protocol (specify the protocol standard unless a proprietary protocol is used)
- c) The communication frequency
- d) The measures taken for key-coding between the remote control and the sound processor(s) to be controlled
- e) The operational range (in centimeters [cm]) between the remote control and the sound processor

Manufacturer shall demonstrate compliance to this section.

5.14.3 Remote control battery

The manufacturer shall describe the following:

- a) Whether the battery is rechargeable or single-use
- b) The battery type
- c) The typical battery lifetime under typical use conditions

Manufacturer shall demonstrate compliance to this section.

5.14.4 Physical properties

The manufacturer shall describe the following:

- a) The size of the device: length x width x height (in mm)
- b) The weight of the device, including batteries (in grams [g])

Manufacturer shall demonstrate compliance to this section.

6 General requirements for implantable parts

NOTE—Consistent with Section 0, the information required in this section is confidential to the manufacturer unless stated otherwise or the information is needed for required regulatory documents summarizing safety and efficacy and/or to fulfill requirements for transparency.

6.1 Biocompatibility

Parts of the device intended to penetrate the surface of the body shall be biocompatible.

In accordance with ANSI/AAMI/ISO 10993-1, implanted parts shall be considered as tissue/bone-contacting for permanent (> 30 days) duration and thus shall be evaluated within a risk management process.

This risk management process may include demonstrating the biocompatibility of the selected materials in potential patient contact by one or more of the following means:

- a) Analogy with published data
- b) Selection of materials (same material, same manufacturer) already shown to be biocompatible by proven clinical use in a similar application
- c) Experience with similar devices already on the market, together with evidence of traceability to the materials used in those devices
- d) Compliance with published procedures for biological evaluation of medical devices

Compliance will be verified by review of the test results and risk analysis provided by the manufacturer.

Manufacturer shall demonstrate compliance to this section.

6.2 Useful life for design and testing purposes

For the practical purpose of the design verification plan for implantable components, the intended useful life of the implantable component shall be a minimum of 10 years. This requirement relates to engineering design and testing considerations and does not limit the intended design life of a design to 10 years.

Manufacturer shall demonstrate compliance to this section.

6.3 Electromagnetic compatibility (EMC)

The electromagnetic compatibility of the implantable device shall be addressed for the electromagnetic characteristics of the intended use environments using appropriate test methods. Testing shall include protection from proximity fields due to radio-frequency emitters such as mobile devices, electronic article surveillance (EAS) systems, and radio-frequency identification (RFID) equipment. Testing shall be conducted using best engineering practices and the test methods shall be sufficiently described and justified.

Manufacturer shall demonstrate compliance to this section. Compliance will be verified by review of the test results and documentation (including risk analysis) provided by the manufacturer.

NOTE—ISO 14708-3 can be considered for use to demonstrate compliance to this section.

6.4 Surface features

Surface features of implantable component(s) shall not cause unacceptable risk (including excessive reaction or inflammation) to the patient during surgical implantation, the intended use of device, and explantation. Where required, test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “low.”

Manufacturer shall demonstrate compliance to this section.

6.5 Safety of electrode insertion

The electrode array shall be designed and tested in five to ten human temporal bones to reasonably maintain the array shape, minimize unintended placement of the array such as cochlear compartment translocation and trauma as evidenced by histological testing.

Separate insertion force testing with a synthetic cochlea should be used to provide verification of insertion force as compared to approved marketed array(s) from the same manufacturer under reproducible test conditions. Seven test samples for the evaluation of the pending array in synthetic cochlea should be used.

Manufacturer shall demonstrate compliance to this section.

6.6 Safety of implantable batteries

If the implantable system contains a battery, the manufacturer shall provide design information and test descriptions regarding the safety, reliability, and expected lifetime of the battery. Safety considerations related to the battery under single-fault failure conditions shall also be described.

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “high.”

Manufacturer shall demonstrate compliance to this section.

6.7 Protection against external electrical hazards for fully implantable systems

For fully implantable devices, the following four leakage current tests in IEC 60601-1 shall be performed at the system level with interconnected accessories as appropriate to the intended function and the device type classification:

- a) Earth leakage current test
- b) Touch or enclosure leakage current test (to protect the user)
- c) Patient (applied parts) leakage current test
- d) Patient auxiliary leakage current test.

These tests shall be conducted for both normal and single-fault conditions. Thus, all the required leakage current tests as specified in IEC 60601-1 shall be conducted on the system as a whole (i.e., the device, battery, charger and any other accessories or components that can be connected to device).

Additional requirements for protection against electrical hazards according to IEC 60601-1 are detailed in Section 17.1 of this standard. The test sample size shall be one.

Compliance will be verified by review of the test results or other documentation and risk analysis provided by the manufacturer.

Manufacturer shall demonstrate compliance to this section.

6.8 Interconnection of implantable parts

If an implantable part of an implant system is intended to be connected to another implantable device or accessory, the accompanying documentation shall provide information on the connector specifications, assembly instructions, and connector performance determined according to Section 23.1.9.

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “high.”

Manufacturer shall demonstrate compliance to this section.

NOTE—There is no known cochlear implant system currently available that uses implantable connectors. The intent of this section is to ensure that the manufacturer provides the necessary information on appropriate connectors, assembly procedures, and performance testing for future systems.

6.9 Electronic assembly life test

As part of the design verification process, the electronics assembly shall be subjected to a 1,000 hour steady state life test per MIL-STD 883H, Method 1005.9. This is a steady-state powered test performed at 125 °C.

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “high.”

Manufacturer shall demonstrate compliance to this section.

7 General requirements for non-implantable parts

NOTE— Consistent with Section 0, the information required in this section is confidential to the manufacturer unless stated otherwise or the information is needed for required regulatory documents summarizing safety and efficacy and/or to fulfill requirements for transparency.

7.1 Biocompatibility

In accordance with ANSI/AAMI/ISO 10993-1, non-implanted external parts can be in contact with the patient for prolonged periods and thus shall be considered as skin-contacting for permanent duration and thus shall be evaluated within a risk management process.

This risk management process may include demonstrating the biocompatibility of the selected materials in potential patient contact by one or more of the following means:

- a) Analogy with published data
- b) Selection of materials (same material, same manufacturer) already shown to be biocompatible by proven clinical use in a similar application
- c) Experience with similar devices already on the market, together with evidence of traceability to the materials used in those devices
- d) Compliance with published procedures for biological evaluation of medical devices

Compliance will be verified by review of the test results and risk analysis provided by the manufacturer.

Manufacturer shall demonstrate compliance to this section.

7.2 Protection against external electrical hazards

Non-implantable parts of an implant system that are connected to supply mains or can be connected to mains powered devices shall comply with the requirements of IEC 60601-1, unless a requirement in that standard is superseded by a requirement in this standard.

Additional requirements for protection against electrical hazards according to IEC 60601-1 are detailed in Section 17.1 of this standard. The test sample size shall be one.

Manufacturer shall demonstrate compliance to this section.

NOTE—During battery changes of the body-worn part, the cochlear implant system is not powered, but the patient will likely physically handle the batteries and touch the battery terminals. During this procedure, the patient becomes an operator and is not a patient in the sense of IEC 60601-1. Therefore, requirements for DC leakage currents from the battery do not apply during battery changes.

7.3 Protection against hazards associated with external surfaces

External surfaces of non-implantable parts of a cochlear implant system shall comply with Clause 9.3 of IEC 60601-1. The test sample size shall be one.

Manufacturer shall demonstrate compliance to this section.

7.4 External battery safety

Non-implantable batteries shall comply with the requirements of the following standards as applicable:

- a) IEC 60086-4, *Primary batteries—Part 4: Safety of lithium batteries*
- b) IEC 62281, *Safety tests for primary and secondary lithium cells and batteries during transport*
- c) IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes—Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*
- d) United Nations (2009), *Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria*, 5th revised edition.

Test samples shall be selected in accordance with the applicable standard. If the standard does not specify a sample size, then test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “high.”

Manufacturer shall demonstrate compliance to this section.

7.5 Electromagnetic compatibility (EMC)

The non-implantable part of the system shall meet the requirements of IEC 60601-1-2 for all intended use environments.

Protection from proximity fields due to radio-frequency emitters such as mobile devices, EAS systems, and RFID equipment shall be appropriately addressed.

Testing may be performed on the system that includes the implantable as well as the non-implantable parts. Set the implant system to function in a clinically representative way that is sufficiently sensitive, allows incorrect operation to be detected during immunity testing, and generates worst-case emissions during emission testing.

The test sample size shall be one.

Compliance will be verified by review of the test results and documentation (including risk analysis) provided by the manufacturer.

Manufacturer shall demonstrate compliance to this section.

7.6 General requirements for software

7.6.1 Life cycle design

Software for a cochlear implant system or software that falls within the definition of a cochlear implant system shall be designed and validated according to software life cycle process activities compliant with IEC 62304.

Manufacturer shall demonstrate compliance to this section.

7.6.2 Medical device risk management, interoperability, and cybersecurity

Software for the operation, fitting, and maintenance of the cochlear implant system shall be developed in a manner to manage risk, enhance interoperability, and boost cybersecurity of the medical device.

NOTE—Medical device interoperability is the ability of medical devices or their components to exchange and make use of information with each other and with clinical systems in order to safely fulfill an intended purpose. Cybersecurity ensures that appropriate safeguards are in place to reduce the risk of failure because of cyberattack, which could be initiated by the introduction of malware into the medical equipment or by unauthorized access to configuration settings in medical devices.

Manufacturer shall demonstrate compliance to this section.

7.6.3 Clinical accessibility to mapping parameters in both clinical and physical units

Manufacturers shall provide a means by which clinicians may obtain and view the mapping parameters for an individual sound processor fitting expressed in both clinical and physical units (see Section 5.8(b)). Parameters should be both viewable and capable of being printed and/or stored in a readily accessible file format. While it is not essential that this capability be part of the fitting software, the capability to view the fitting parameters in both unit systems should be available to the clinician at the time of fitting and during later review.

Manufacturer shall demonstrate compliance to this section.

NOTE: An example of the utility of expressing mapping parameters in common physical units across devices is provided in Zwolan et al. (2008).

7.7 Requirements for user accessories and clinical tools

Any accessories and clinical tools designed by the manufacturer that directly connect to the sound processor and are regulated as medical devices shall comply with the following standards, as appropriate:

- a) Requirements regarding electrical safety, essential performance, electromagnetic compatibility, and rough edges of IEC 60601-1 and IEC 60601-1-2
- b) Requirements regarding biocompatibility of ANSI/AAMI/ISO 10993-1
- c) Requirements regarding choking, aspiration, and ingestion hazards of small parts and cables of ASTM F963, *Standard consumer safety specification for toy safety*

Manufacturer shall demonstrate compliance to this section.

8 System-level inspection, characterization, and measurement

All measurements shall be performed with the implantable part of the cochlear implant system at a temperature of $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

NOTE—Consistent with Section 0, the information required in this section is confidential to the manufacturer unless stated otherwise or the information is needed for required regulatory documents summarizing safety and efficacy and/or to fulfill requirements for transparency.

8.1 Measurement of output signal characteristics

If applicable, the transcutaneous link shall operate over a distance of $5\text{ mm} \pm 0.5\text{ mm}$ between coil surfaces (equivalent to the skin flap thickness). If the implant system provides alternative output signals, each shall be measured and listed separately. To facilitate connection, the test sample may be unfinished. The accuracy of the amplitude and time measurements shall be better than 5%, taking all errors into consideration.

Manufacturer shall demonstrate compliance to this section.

8.2 Measurement of the output signal amplitude and stimulus timing parameters

A representative sample of the implant system shall have each electrode output connected to a specified load resistor (see Figure 7) and configured according to Section 8.1 for each measurement. The device shall be set to maximum clinically programmable output limits using fitting software. An oscilloscope or other calibrated instrumentation shall be adjusted to analyze the full output at its maximum resolution. The measurement shall be made at the peak of the output signal. In turn, each output shall be connected to the measurement instrument, and the amplitude and stimulus timing parameters shall be measured. The median of the amplitudes and stimulus timing parameters and their range shall be recorded and the results shall be expressed in amperes (A) and seconds (s). The stimulus timing parameters (e.g., phase duration, interphase duration) reported will be dependent on the stimulus waveform used. (See Section 17.5 for possible examples.)

Manufacturer shall demonstrate compliance to this section.

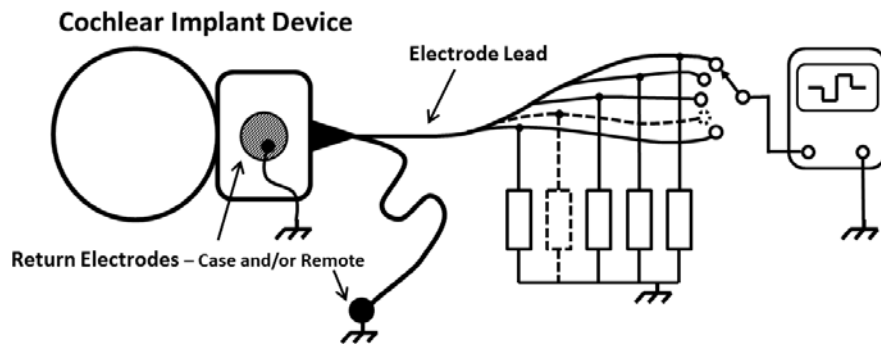


Figure 7—Configuration for measurement of output signal amplitude and impedance

8.2.1 Measurements taken during steady-state operation of the implantable part

The measurements specified in this section shall be repeated for all electrode outputs, using a nominal load resistor for the system as specified by the manufacturer. The manufacturer should note the resistance used and the specified range.

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “low.”

The following shall be verified and documented:

- That the accuracy of the stated stimulus output range complies with the technical specification of the device
- That the accuracy of conversion between clinical units and physical units of stimulation complies with the technical specification of the device
- That the accuracy of the stated stimulus timing parameters and stimulus rate complies with the technical specification of the device
- That the accuracy of routing of outputs to appropriate electrodes and the appropriate isolation of signals across electrodes complies with the engineering design specification of the device
- That the direct current leakage complies with the acceptable limit specified in Section 17.2 (Direct current leakage limit under use conditions)
- That the charge density limits and charge limits comply with Section 17.3 (Charge density limits and charge limits)
- That the charge balancing complies with Section 17.5 (Charge balancing requirements)
- Using the proposed processing strategy and typical mapping output levels and durations, that the stimulation output levels stay within safe limits during active signal processing
- That under steady and nominal power conditions, disruption of the data link does not produce output levels that exceed the safe current density limits specified in Section 17.3

Manufacturer shall demonstrate compliance to this section.

8.2.2 Measurements taken during power-up operation of the implantable part

It shall be verified and documented that under the following conditions, the implantable part does not produce aberrant or transient output levels that exceed the safe current density limits specified in Section 17.3 or violate the charge-balancing requirements of Section 17.5:

- Power-on or switch-on condition with headpiece in place (the condition when the power source is applied to the external components)
- Headpiece applied after steady-state operation of the external parts

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “low.”

These tests shall be conducted with the nominal resistive load specified by the manufacturer on all output terminals shown in Figure 7. The measurements shall be made for each device output individually.

Manufacturer shall demonstrate compliance to this section.

8.2.3 Measurements taken during power-down operation of the implantable part

It shall be verified and documented that under the following conditions, the implantable part does not produce transient output levels that exceed the safe current density limits specified in Section 17.3 or violate the charge-balancing requirements of Section 17.5:

- a) Power-off or switch-off condition with headpiece in place (the condition when the power source is removed from the external components)
- b) Headpiece removal with no replacement during steady-state operation
- c) Transient removal and replacement of headpiece during steady-state operation of the system
- d) Battery rundown condition during steady-state operation

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “low.”

These tests shall be conducted with the nominal resistive load specified in Section 5.7 on all output terminals shown in Figure 5. The measurements shall be made for each device output individually.

Manufacturer shall demonstrate compliance to this section.

8.3 Impedance measurement accuracy

If the implant system allows an impedance measurement (either by telemetry or by direct measurement), the manufacturer shall specify the accuracy of the impedance measurement for the three load resistor values representing a typical impedance load, a load at the lower end and a load at the upper end. The measurement conditions shall be chosen to reflect normal clinical practice and shall be described in the documentation. The measurement shall be repeated for every electrode output (see Figure 7). The accuracy of the impedance measurement shall be expressed as a percentage. The voltage compliance of the current source(s) shall be specified.

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “low.”

Manufacturer shall demonstrate compliance to this section.

8.4 Inductive link characterization

If the implant system uses an inductive link to transmit power and data among various components (e.g., between the sound processor and the implant electronics), the manufacturer shall specify the range of skin flap thickness over which link integrity will be maintained within acceptable performance limits. As applicable, acceptable performance limits may be defined in terms of data integrity and also in terms of implant voltage. Data integrity shall be established in both the forward and reverse telemetry directions in order to provide for a more difficult test condition than either the forward or reverse telemetry directions alone. All critical parameters/settings that influence the inductive link characterization should be specified, as applicable.

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “low.”

Manufacturer shall demonstrate compliance to this section.

8.5 Sound processor battery testing

NOTE—This section applies to characterization of operational performance of primary and secondary batteries used to power the sound processor of the CI system.

Test samples shall be selected in accordance with Section 8.6. The sample size category for the tests in this section is “low.”

8.5.1 Typical system operation time on single battery charge

The objective of this test is to measure battery life and power consumption at the sound processor battery terminals using standardized conditions and system default settings with a sound processor coil to implant coil separation of 5 mm $\pm$ 0.5 mm (equivalent to the skin flap thickness). This test is applicable to all primary and secondary batteries of any chemistry for each battery size.

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “low.”

The test should be performed with fresh batteries and at an ambient temperature of 21 °C $\pm$ 3 °C

The test procedure is as follows:

- 1) Set the sound (or speech) processor to the manufacturer-defined default values for sensitivity and volume, as applicable. (Some manufacturers might specify only one or the other.)
- 2) Using the default stimulation parameters, program the device to effect an output amplitude set to the typical upper and lower program level for the average patient population.

NOTE—Terminate the electrodes in an impedance to ensure they are in voltage compliance. Use the nominal manufacturer specified load impedance.

- 3) Further program the device to effect the default stimulus duty cycle, total stimulation rate, and pulse width setting. Visual and audio alarms should be programmed off.
- 4) Deactivate or do not use accessories.
- 5) Apply a speech test signal with a free-field sound pressure level of 65 dBA (slow). The international speech test signal (ISTS) shall be used as the test signal, as defined in IEC 60118-15:2012, Clause 6.2. The ISTS is freely available from the website of the European Hearing Instrument Manufacturers Association (EHIMA) (www.EHIMA.com).
- 6) Set the sound processor coil to implant coil separation to 5 mm $\pm$ 0.5 mm, measured between the external surfaces of the coil enclosures (equivalent to the skin flap thickness).

Compliance will be verified as follows:

- a) Inspect the manufacturer's specifications, and confirm that the correct default values and input and output dynamic range settings have been used.
- b) Measure and record the power consumption at the battery terminals while powering the system with a new charged manufacturer-recommended battery.
- c) Measure and record the battery life until stimulation stops permanently because of battery depletion.
- d) Repeat for all marketed battery size options.
- e) Report the settings, measured power consumption, and battery life for all recommended battery size options. This information shall also be included in the product data sheets (see Section 12.1).

Manufacturer shall demonstrate compliance to this section.

8.5.2 Rechargeable battery fade test

The objective of this test is to measure the reduction in capacity of rechargeable batteries that occurs after a number of charge/discharge cycles. The principle of this test method is to use a combination of accelerated life cycles overlaid with more “realistic” discharge conditions every 20th cycle for a total of 400 cycles. It is allowable for less cycle data to be collected as long as there is enough data to allow for linear extrapolation of the result to 400 cycles.

Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is “low.”

The test shall be performed with new rechargeable batteries and at an ambient temperature of 21 °C $\pm$ 3 °C.

The test results shall be displayed as discharge capacity and charge coefficient (charge capacity [milliampere hours {mAh}] divided by discharge capacity) as a function of cycle count. A cycle is defined as a full charge followed by a full discharge, as specified in the stated procedure.

The test procedure is as follows:

- 1) Discharge each battery at the “C/2” rate (i.e., current drain rate to discharge a fully-charged battery in 2 hours) to 0 % battery capacity.
- 2) Rest the battery for up to 30 minutes.
- 3) Charge at C/2 rate to full battery capacity; match the charge rate and voltage to those of the system being tested, or use the charger for the system being tested.
- 4) Rest the battery for up to 30 minutes.
- 5) Discharge at C/2 rate to 0 % battery capacity or match the cut-off voltage to that of the system being tested.
- 6) Repeat Steps 2) through 5). Repeat 18 times.
- 7) Rest the battery for up to 30 minutes.
- 8) Discharge at C/10 rate to 0 % battery capacity, or match the cut-off voltage to that of the system being tested.
- 9) Rest the battery for up to 30 minutes.
- 10) Charge at C/10 rate to full battery capacity; match the charge rate and voltage to those of the system being tested, or use the charger for the system being tested.
- 11) Rest the battery for up to 30 minutes.
- 12) Discharge at C/10 rate to 0 % battery capacity, or match the cut-off voltage to that of the system being tested.
- 13) Repeat Steps 1) through 12). Repeat 19 times.

Manufacturer shall demonstrate compliance to this section.

NOTE—This test procedure results in 19 cycles of a full charge, then discharge at a C/2 discharge rate, and then 1 cycle at a C/10 discharge rate. This process flow is performed 20 times for a total of 400 cycles.

8.6 Risk-based selection of test sample size

8.6.1 General requirements

Many of the sections of this standard require tests to be performed on samples of the device to demonstrate that the device meets the requirements of this standard with the appropriate level of confidence. The selection of the appropriate level of confidence considers the level of patient harm and the likelihood of the harm to the patient occurring for a given failure mechanism, considering the variability of the performance of the device due to uncertainty in testing and variation in test units. All sources of test unit variation, including both long-term and short-term effects of variation and uncertainty that could affect the results, should be considered. The test protocol shall describe the main sources of variability and justify the capability of the test procedure and the validity of the sample size used for the statistical analysis method and required confidence level.

The required sample size shall be calculated according to the required conformance proportion and confidence levels, the type of test data, and the proposed statistical analysis methodology.

If a patient risk-based approach for reliability prediction is used by the manufacturer in the design process (such as a failure modes and effects analysis [FMEA], failure modes, effects and criticality analysis [FMECA], or equivalent), manufacturers may use their risk process for determining sample sizes, provided the results are statistically equivalent or superior to the requirement in this section.

The process described by this section supports three paths for determining the sample size. In all paths, the basic process is to determine the required confidence and proportion conforming, then to select the statistical analysis method, and finally to calculate the required sample size.

This process is shown by the flow chart in **Figure 8**. The three possible paths are described below:

- Path 1: “Type tests” only require tests on a single sample to demonstrate compliance to the standard. Tests that can use this path include
 - o Tests for the presence or absence of a feature, or
 - o Electromagnetic compatibility (EMC), electromagnetic interference (EMI), ultrasonic immunity, and certain magnetic resonance imaging (MRI) tests, or
 - o Other tests as specified as ‘type tests’ in this standard

- Paths 2 and 3: The other two paths require the determination of the minimum confidence and conforming proportions to determine the sample size. The selection from these two paths is at the discretion of the manufacturer. The two paths are numbered 2 and 3 in **Figure 8**:
 - o Path 2 uses the “sample size category” of high, medium, or low stated in many sections of this standard. The first step for this path is defined in Section 8.6.2.
 - o Path 3 involves “determination of patient risk.” The first three steps for this path are defined in Section 8.6.3.

After the required sample size has been determined according to one of the three paths, the tests can be performed and the results can be analyzed and interpreted to determine compliance according to the acceptance criteria in the relevant section of this standard.

Manufacturer shall demonstrate compliance to this section.

NOTE—The above process does not replace the risk management process that is in place as part of the manufacturer's quality system.

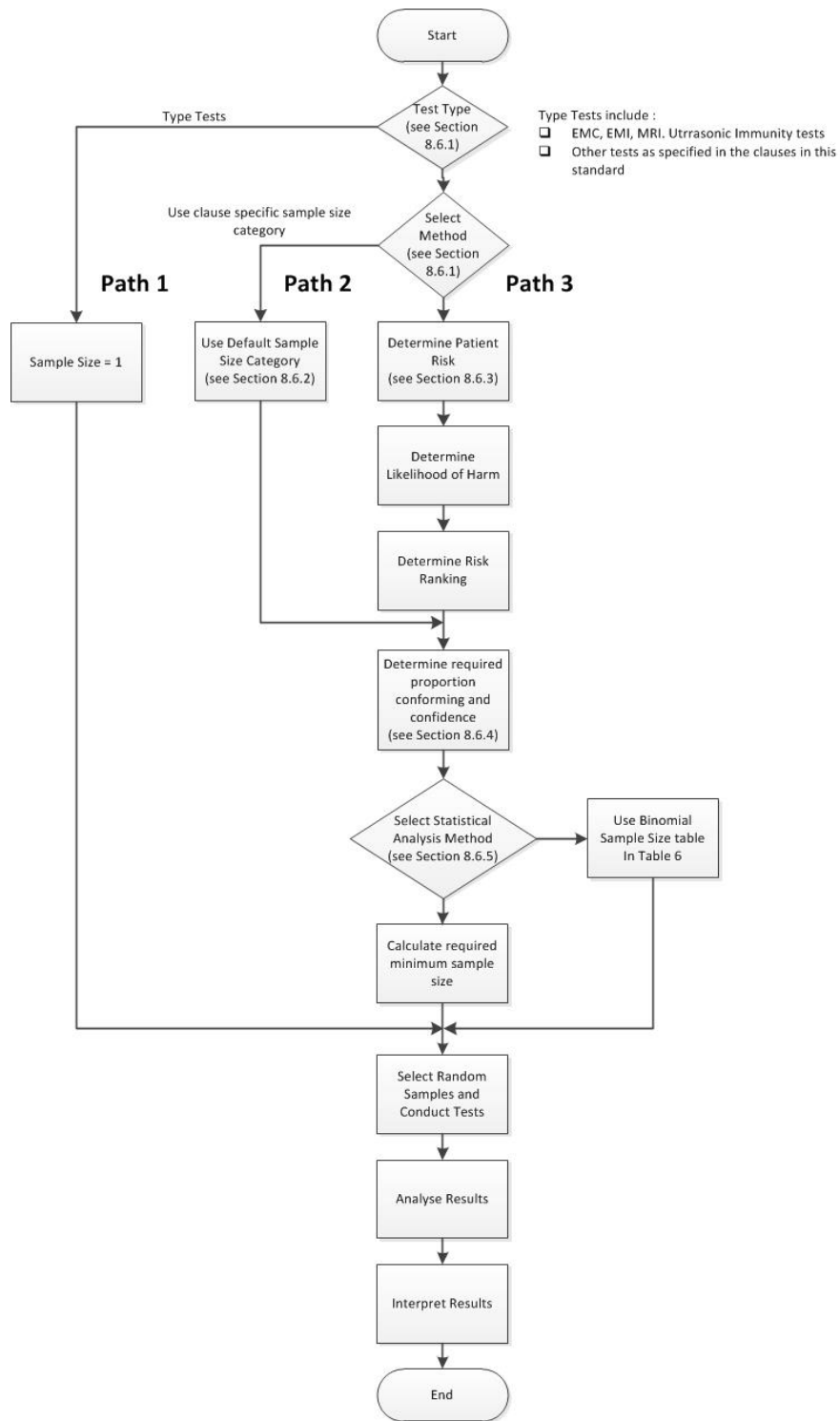


Figure 8—General process for determining sample size

8.6.2 Default levels of 'sample size category' – Path 2

In general, sections requiring specific tests within this standard state a default sample size category and refer to this general section (Section 8.6) for guidance in determination of sample size. If this default sample size category is used, then the next step would be to determine the conforming proportion and confidence proportion using Section 8.6.4. In this case, Section 8.6.3 can be skipped.

8.6.3 Determination of risk ranking using design analysis – Path 3

The design analysis determination of the risk ranking described in this section requires the manufacturer to analyze their design to determine the patient risk based on the severity of harm that is possible if the device fails and on the probability of occurrence of the harm. The tables below are used to determine the risk ranking. After the risk ranking is determined, the required conforming and confidence proportions can be determined according to Section 8.6.4.

The first step is to determine the severity of harm to the patient should the device fail the requirement in this standard. Table 1 is used to determine the severity of harm rank for such a failure.

Table 1—Severity of harm in rank order

Rank	Severity of Harm System and Hardware	Description
5	Catastrophic <i>Life-threatening</i>	The hazard has the potential of resulting in death. To eliminate the hazard, the device must be removed or replaced.
4	Critical <i>Permanent impairment</i>	The hazard has the potential of resulting in critical permanent injury or tissue damage. Permanent physiological damage to the cochlear tissue. Device explantation
3	Serious <i>Injury or impairment requiring surgical intervention or hospitalization</i>	The hazard has the potential of resulting in injury requiring medical or surgical intervention.
2	Minor <i>Temporary injury or impairment, not requiring surgical intervention or hospitalization</i>	The hazard has the potential of resulting in temporary injury NOT requiring surgical intervention or hospitalization. Impaired performance or pain that can be eliminated or improved by clinical reprogramming or counselling.
1	Negligible <i>Temporary discomfort</i>	The hazard has the potential of resulting in temporary or short-term undesired stimulation that can be resolved by the recipient or clinician adjusting device settings. Non-operation or impaired operation of ancillary functions without requiring explant or replacement surgery.

Having determined the severity of the potential harm, the next step is to determine the likelihood of the failure occurring, using the occurrence ranking described in Table 2. The probability of occurrence (Q) of harm is based on the expected probability of the device failing in the field. This probability is initially determined based on risk analysis using field failure rate data or previous tests on predicate devices.

Table 2—Occurrence-of-harm definitions and ranking

Rank	Occurrence of Harm (Qualitative)	Probability of Occurrence (Q) (Quantitative)	
		As Probability	As Percentage
5	Frequent	$Q > 0.1$	$Q > 10\%$
4	Probable	$10^{-2} < Q \leq 0.1$	$1\% < Q \leq 10\%$
3	Occasional	$10^{-4} < Q \leq 10^{-2}$	$0.01\% < Q \leq 1\%$
2	Remote	$10^{-6} < Q \leq 10^{-4}$	$0.0001\% < Q \leq 0.01\%$
1	Improbable	$Q \leq 10^{-6}$	$Q \leq 0.0001\%$

The risk ranking (see Table 3) is determined by the multiplication of the occurrence ranking (from

Table 2) by the severity-of-harm rank (from Table 1). The result is used to determine the risk levels of high, medium, and low, as defined in Table 4 (Risk definitions).

Table 3—Risk ranking*

		Risk Ranking (RR)				
Occurrence of Harm Ranking (Table 2)	5	5	10	15	20	25
	4	4	8	12	16	20
	3	3	6	9	12	15
	2	2	4	6	8	10
	1	1	2	3	4	5
		1	2	3	4	5
		Severity of Harm Ranking (Table 1)				

*The risk rankings in each cell of Table 3 represent the Severity Ranking x the Occurrence Ranking.

Table 4—Risk definitions

Risk Definitions Based on Risk Ranking (RR) (Table 3)	High Risk $RR \geq 10$	Medium Risk $3 < RR < 10$	Low Risk $RR \leq 3$
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After determining the risk level of high, medium, or low, the next step is to determine the required conforming and confidence proportions (Section 8.6.4).

8.6.4 Determination of the required conforming and confidence proportions – Paths 2 and 3

Table 5 shows the required statistical conformance (R) and confidence proportions (C) for a given risk level.

Table 5—Required conforming and confidence proportions for a given risk level

Risk Level (Table 4)	Conforming Proportion	Confidence Proportion
High Risk	R = 90%	C = 95%
Medium Risk	R = 80%	C = 90%
Low Risk	R = 70%	C = 70%

After determining the required conforming and confidence proportions, the next step is to select the analysis method and determine the sample size (Section 8.6.5).

8.6.5 Selection of analysis method and determination of sample size – Paths 2 and 3

After the required conformance and confidence proportions have been determined, the statistical analysis method and hence the sample size can be determined.

The sample size used shall comply with one of the following:

- a) Attributes that have no variability only require a sample size of one. An example would be a parameter such as the presence or absence of a feature.
- b) Unless otherwise specified in this standard, a minimum sample size of one device shall be used for type tests.
- c) For EMC, EMI, MRI, and ultrasonic immunity tests, a sample size of one device or system is acceptable unless a larger sample size is specified in another section of this standard.
- d) For other cases, the statistical analysis method and sample size are selected using one of the approaches below:
 - i. A binomial analysis method may be used when the result of a test on a sample is a binomial discrete attribute (e.g., pass or fail). Table 6 shows the appropriate sample sizes when zero failures are allowed. The Binomial analysis also supports failures greater than zero but requires higher sample sizes.
 - ii. A normal distribution statistical model may be used when the results of a test are continuous data. This method could require fewer samples than the binomial analysis method but requires some knowledge of the distribution of the results.
 - iii. Other methods that demonstrate that the results meet the required confidence and conforming proportions are acceptable.

The statistical analysis method, assumptions and sample size used in each test of this standard and a justification for this selection shall be documented. If the binomial analysis method is used, then justification for the analysis method is not required.