American National Standard

ANSI/AAMI CI86:2017

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

AAMI
Advancing Safety in Healthcare Technology

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.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

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

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards and recommended practices by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

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

- 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.
- 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.

NOTE—This document contains active links. To return to your previous location after following an active link, use Alt (left arrow).

Published by

AAMI
4301 N. Fairfax Dr., Suite 301
Arlington, VA 22203-1633

© 2017 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 978-1-57020-662-7

Contents

Page

Glossary of equivalent standards v

Committee representation vi

Acknowledgments vi

Foreword vii

1 Scope 1

2 Normative references 2

3 Definitions 4

4 Units, abbreviations, and symbols 12

5 General requirements for characterizing a cochlear implant system 14

6 General requirements for implantable parts 27

7 General requirements for non-implantable parts 29

8 System-level inspection, characterization, and measurement 31

9 Implantation support (RESERVED FOR FUTURE VERSIONS) 42

10 Post-implantation testing, *in vivo* assessment, and analysis of failed devices 42

11 Reliability monitoring and reporting 45

12 Information on use, warnings, and hazards 64

13 General arrangement of the packaging system 70

14 Markings on the packaging system and the cochlear implant device 70

15 Safety from unintentional biological effects of the cochlear implant system 76

16 Safety of secondary features of the cochlear implant system 76

17 Safety of electrical stimulation 77

18 Safety of implantable energy sources 82

19 Safety from heat sources 83

20 Safety from unintended effects caused by the device 85

21 Safety and device immunity during magnetic resonance imaging 87

22 Device immunity to external stresses caused by medical treatment and procedures 92

23 Device immunity to stresses of mechanical forces 97

24 Device immunity to stresses caused by atmospheric pressure changes 107

25 Device immunity to stresses caused by temperature changes 109

26 Non-implantable device immunity to stresses caused by environment and usage 110

Annex A (informative) Clinical identification and management of cochlear implant device failures 123

Annex B (informative) Clinical checklist prior to explantation Signs and symptoms checklist 125

Annex C (informative) Returned implant analysis 129

Annex D (informative) Indications of performance decline 135

Annex E (informative) Reliability reporting to regulatory bodies 136

Annex F (informative) Pareto analysis 145

Annex G (informative) Failed component return rate (FCRR) graphic and table 147

Annex H (informative) Reliability reporting template for the public and clinical community **149**

Annex I (informative) Product specification data sheets **152**

Annex J (informative) Mechanical testing of leads and interfaces to case bodies **158**

Annex K (informative) Logic flow diagram of the relationships between the required testing, explant category classification, and reliability reporting to both regulatory bodies and the public **161**

Bibliography **167**

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:

Co-Chairs:
Cedric Mark Navarro
Julie Verhoff, AuD, PhD

Members:
Douglas D. Backous, MD, Swedish Medical Center
Kevin Crowe, BSc(Eng), Cochlear Ltd.
Vasant Dasika, PhD, FDA/CDRH
Bruce J. Gantz, MD, University of Iowa Hospitals and Clinics
Eric Khosravi, MAS, MSQA, Oticon Medical
Bomjun Kwon, PhD, Gallaudet University
Anil K. Lalwani, MD, American Neurotology Society
Cedric Mark Navarro, Advanced Bionics LLC
Michael Pecht, PhD, University of Maryland College Park
Mark J. Syms, MD FACS, Arizona Ear Center
Julie Verhoff, AuD, PhD, The River School / Chattering Children
Fan-Gang Zeng, PhD, University of California at Irvine
Martin Zimmerling, PhD, MED-EL GmbH
Teresa A. Zwolan, PhD, University of Michigan

Alternates:
Sean Bundy, Cochlear Ltd
Charles Finley, PhD, Advanced Bionics LLC
Srinivas Nandkumar, PhD, FDA/CDRH
Edward Overstreet, PhD, Oticon Medical
Manfred Pieber, MSc, MED-EL GmbH
William F. Regnault, PhD, FDA/CDRH
Bhanu Sood, MSc
Liliane L. Tessa, BS, University of Maryland

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.

Acknowledgments

The committee gratefully acknowledges James (Jim) Kane, PhD, and William (Bill) Regnault, PhD, of the U.S. Food and Drug Administration for their contributions to the development of an American National Standard for cochlear implants. Drawing on their experience from their regulatory careers, they have broadened the standard to better promote safe and efficacious applications of cochlear implants. Jim served as chief advocate and co-chairman of the committee from its inception to his retirement in 2013. Bill's extensive technical expertise and critical thinking influenced numerous aspects of this standard. Their commitment of time and effort attests to their dedication to patient welfare and is greatly appreciated.

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.

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

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

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

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.

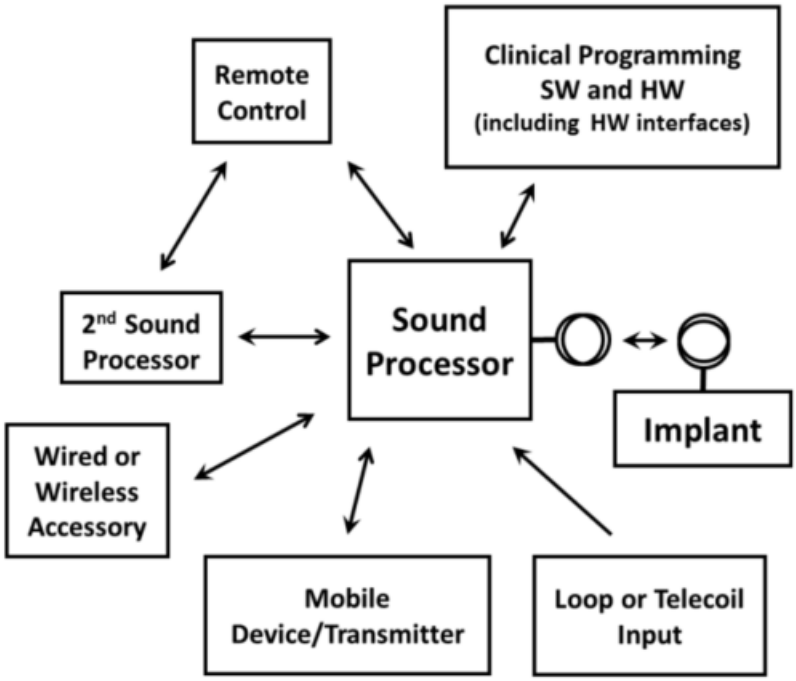


Figure 1—Example block diagram of device system hardware and software components and connections/links

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

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.

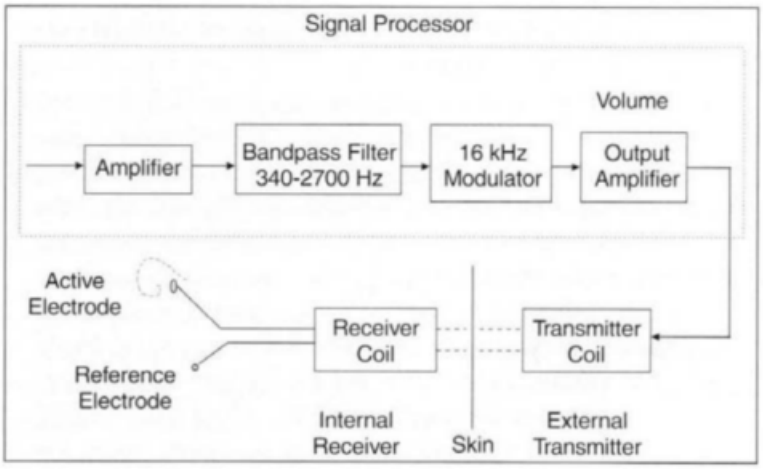


Figure 2—High-level overview block diagram of a simple cochlear implant system

[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.

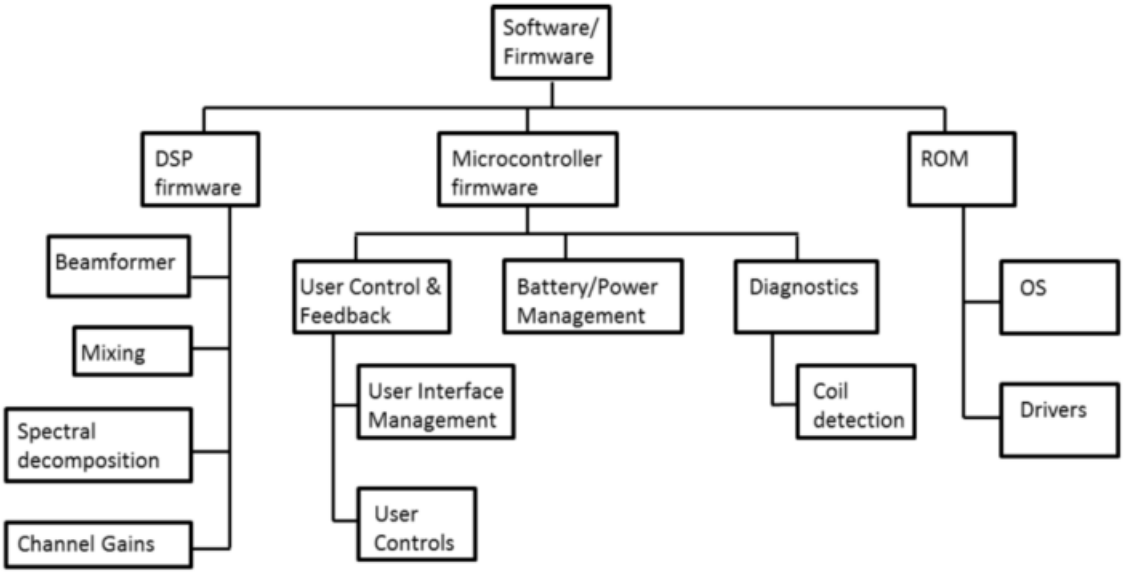


Figure 3—Example of a system software architecture diagram for a sound processor

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

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

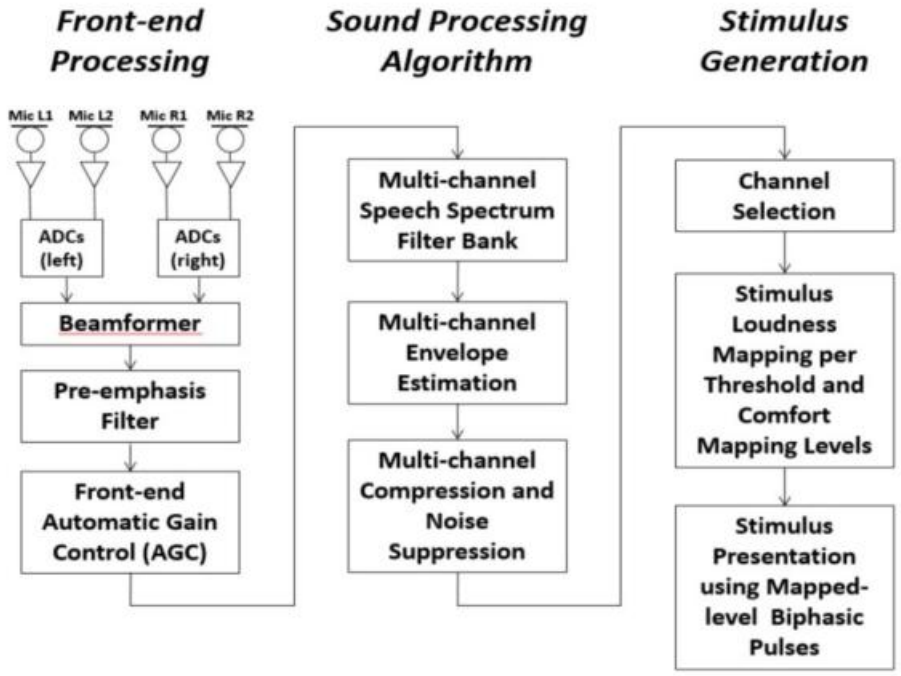


Figure 4—Diagram of a detailed end-to-end signal-path overview block diagram

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.

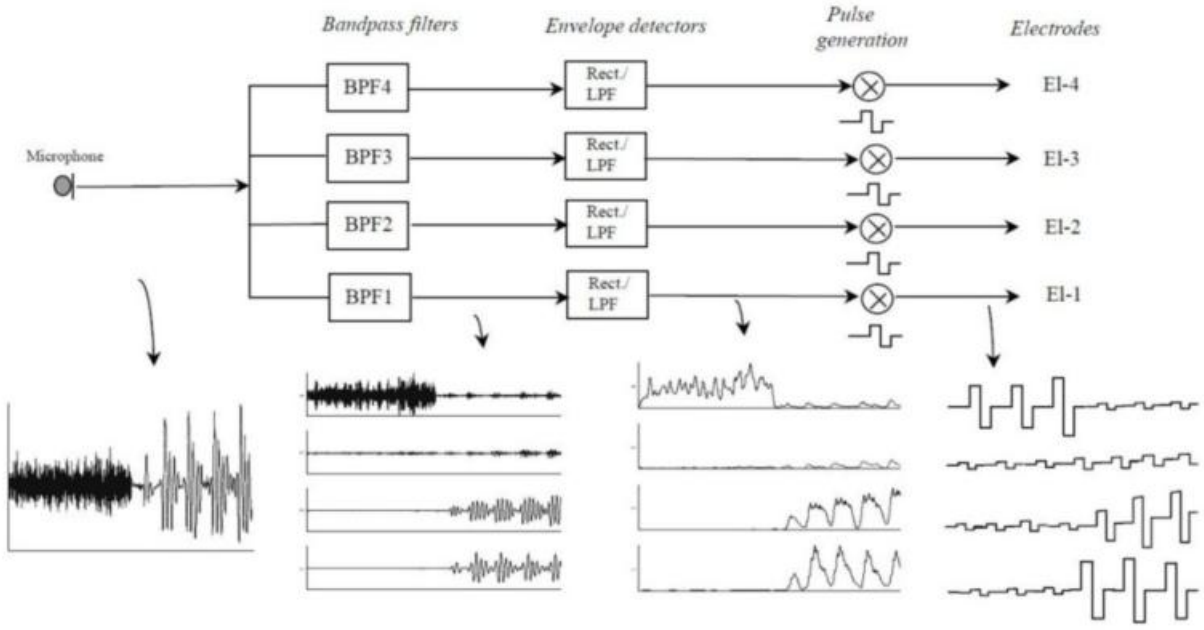


Figure 5—Example of a block diagram of the continuous interleaved sampling (CIS) sound coding strategy (reprinted with permission from Loizou PC (1998) Mimicking the Human Ear in IEEE Signal Processing MagazineSept, pp 101-130)

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.

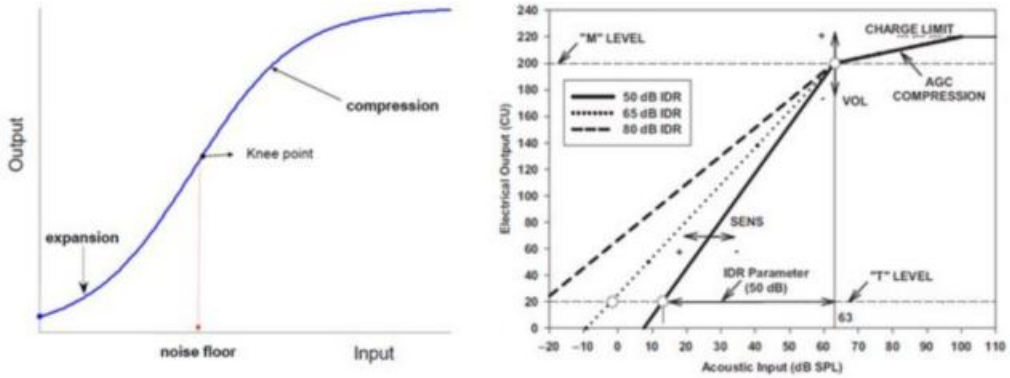


Figure 6—Examples of various mapping functions

[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 mm^2)
    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 mm^2), if applicable
    vii. The geometric surface area of the smallest and largest stimulating reference electrodes (in mm^2), 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 °C ± 2 °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 mm ± 0.5 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.

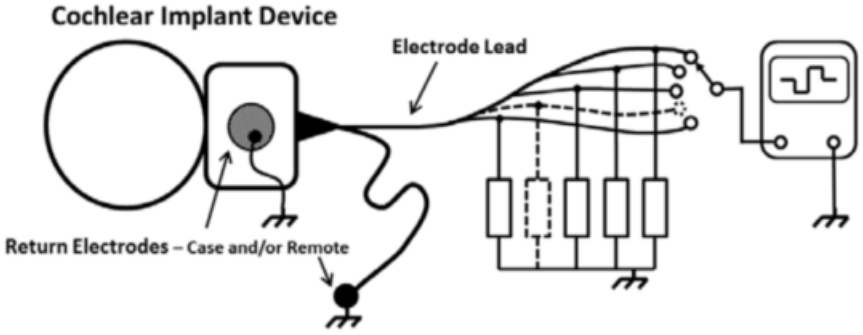


Figure 7—Configuration for measurement of output signal amplitude and impedance

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:

a) That the accuracy of the stated stimulus output range complies with the technical specification of the device
b) That the accuracy of conversion between clinical units and physical units of stimulation complies with the technical specification of the device
c) That the accuracy of the stated stimulus timing parameters and stimulus rate complies with the technical specification of the device
d) 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
e) That the direct current leakage complies with the acceptable limit specified in Section 17.2 (Direct current leakage limit under use conditions)
f) That the charge density limits and charge limits comply with Section 17.3 (Charge density limits and charge limits)
g) That the charge balancing complies with Section 17.5 (Charge balancing requirements)
h) 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
i) 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:

a) Power-on or switch-on condition with headpiece in place (the condition when the power source is applied to the external components)
b) 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 ± 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 ± 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 ± 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 ± 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:

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

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
    - Tests for the presence or absence of a feature, or
    - Electromagnetic compatibility (EMC), electromagnetic interference (EMI), ultrasonic immunity, and certain magnetic resonance imaging (MRI) tests, or
    - 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**:
    - 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.
    - 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.

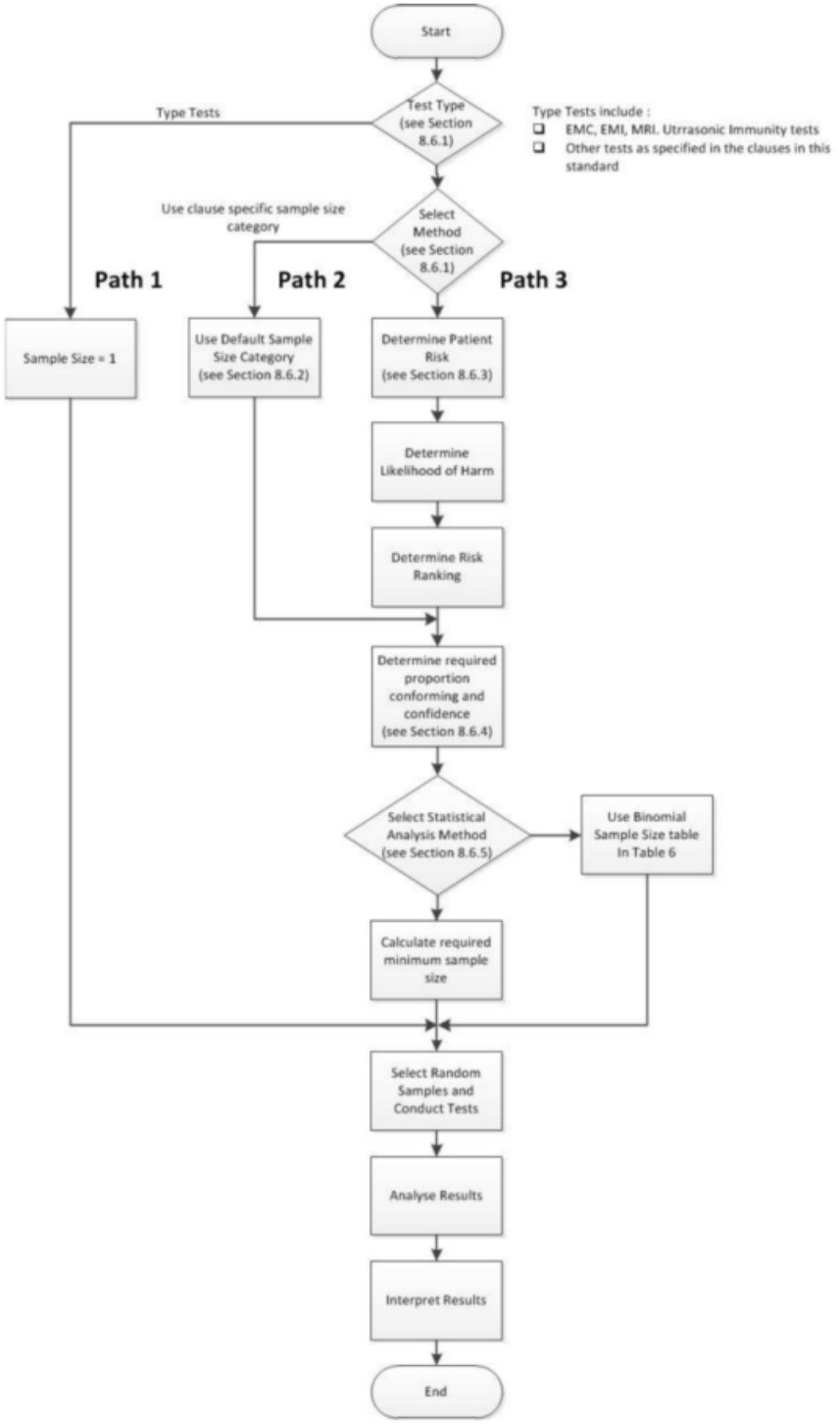


Figure 8—General process for determining sample size

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 Section8.6.4. 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 *Life-threatening*	The hazard has the potential of resulting in death. To eliminate the hazard, the device must be removed or replaced.
4	Critical *Permanent impairment*	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 *Injury or impairment requiring surgical intervention or hospitalization*	The hazard has the potential of resulting in injury requiring medical or surgical intervention.
2	Minor *Temporary injury or impairment, not requiring surgical intervention or hospitalization*	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 *Temporary discomfort*	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	Medium Risk	Low Risk
	$RR \geq 10$	$3 < RR < 10$	$RR \leq 3$

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 that 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.

Table 6—Minimum sample sizes for prescribed levels of conforming and confidence proportions for a binominal test with zero failures

Conforming Proportion	Confidence Proportion	Sample Size (for a binomial test with zero failures)
R = 90%	C = 95%	29
R = 80%	C = 90%	11
R= 70%	C = 70%	4

NOTE—The sample sizes listed in Table 6 are minimums and generally have low statistical power. The risk here is with the manufacturer, as low power means a greater chance of failing a test even though the true non-conformance rate is above the requirement. Some manufacturers might want to increase the overall sample size and allow more than zero failures in order to increase the power, and thus reduce the risk of failing the test.

Manufacturer shall demonstrate compliance to this section.

NOTE—Manufacturers can determine their own policies for determining sample sizes for design verification and validation tests using a risk-based approach. Alternative statistical techniques can be used to determine the sample sizes to achieve the above confidence and reliability. The rationale for the sample sizes used must be documented in the test protocol.

8.7 Design verification tests for system components

A design verification protocol shall be defined by the manufacturer and used to confirm device operation following various tests of system components, as specified in the standard. System components include any implantable or non-implantable components, including body-worn and non-body-worn components, and accessories that support implantation, fitting, or maintenance of the system. Cables and connectors, both implantable and non-implantable, are included.

The documentation shall include the design verification protocol, including a description of the objectives, test parameters, and acceptance criteria.

A simulated-use design verification protocol shall be performed at the system level. The protocol shall include specification testing sufficient to ensure the following:

a) The risk to the patient remains acceptable (e.g., acceptable current leakage, acceptable charge balancing).
b) The technical specifications and performance requirements (with pass/fail conditions and allowable tolerances, as applicable) for the device, implantable and non-implantable components (both body-worn and non-body-worn), cables, connectors, and accessories are met.
c) The results of the tests demonstrate that the device meets the manufacturer's specified lifetime of the device, when relevant (e.g., leakage current levels meet the manufacturer's specification after the aging tests).

In cases where destructive tests are specified by this standard, the test results shall confirm the appropriateness of the device design and the manufacturer's implantable component specifications in meeting the requirements of the standard.

Manufacturer shall demonstrate compliance to this section.

8.8 Reporting requirements for validation and verification testing

The names and serial numbers (if appropriate) of all test equipment, analytical instrumentation, materials, software, and computers used for testing during this verification (e.g., environmental chamber, micrometer) shall be documented in the report.

If more than one of the same piece of equipment is used, the quantity shall be specified.

There shall be current calibration and maintenance records for all equipment used for verification testing or measurement. This information shall be included in the report. Supporting documentation (e.g., service summaries, calibration certificates, lab book reports) should be included as an appendix of the verification report or controlled and referenced in the report.

Manufacturer shall demonstrate compliance to this section.

9 Implantation support (RESERVED FOR FUTURE VERSIONS)

NOTE—This section is left intentionally blank in the present version. In future revisions of the standard, this section will address surgical tools, fixtures, and other items in support of or related to surgical implantation. Specific items to be included are biocompatibility of tools and materials, sterilization methods, and a description of the availability of surgical support.

10 Post-implantation testing, *in vivo* assessment, and analysis of failed devices

NOTE—See Annex K for a logic flow diagram of the relationships between the required testing, explant category classification, and reliability reporting to both regulatory bodies and the public.

10.1 Functional evaluation of a device *in vivo*

The manufacturer shall establish procedures to perform a functional evaluation of implantable components *in vivo*. Based upon these procedures, a clinical care plan can be established by the health care provider. The objective of this requirement is for the manufacturer to provide to the clinic device-specific procedures to enable the clinician to manage problematic and/or failed devices.

Manufacturer shall demonstrate compliance to this section.

NOTE—Beyond a minimum requirement that the plan include post-operative assessment of a device *in vivo*, the following recommendations do not restrict the scope of the plan:

a) The plan should provide for the testing of the functional components of the implantable medical device as well as the integrated function of these components as they would operate in the medical application of the device.
b) In all cases, the testing plan should seek to protect the patient from harm and/or discomfort as a consequence of the testing procedure, especially in the case of devices operating outside of engineering design specifications. The procedure should address and minimize the possibility of causing harm during testing procedures conducted under sedation or anesthesia, when behavioral responses are suppressed. To these ends, a possible endpoint in the test plan is that further device testing is not warranted or possible and/or exposes the patient to excessive risk.
c) The plan may include, but not be limited to, measurement procedures involving patient behavioral reports, back telemetry of internal data from the device itself, measurement of electrical stimulation potentials from the scalp, measurement of evoked biological responses, and/or other means of device monitoring as might become available.
d) To the extent possible, guidelines for identifying a normally functioning device, using the measures described above, should be provided.

In anticipation that the functionality of any implantable component might come into question, the manufacturer and clinicians should develop comprehensive support plans, including the following key elements, which are further described in Annex A:

i. Preoperative
    1. Counseling, including information regarding device reliability and the possibility of device failure
    2. Obtainment of case history information and speech perception and speech/language testing results to establish the expected outcome
    3. Conducting of speech recognition testing with appropriate amplification

4. Radiologic and electrophysiologic testing to develop the prognosis for electric stimulability

ii. Intraoperative
   1. Radiologic and electrophysiologic (e.g., impedance, ECAP, eSRT, EABR) testing to evaluate the placement and function of the implanted device, including the electrode array
   2. Ensure documentation shall be recorded and maintained of the implantation surgery

iii. Post-operative
   1. Regular examination of external equipment to ensure appropriate function
   2. Regular administration of impedance telemetry to monitor the function of the electrodes in the array
   3. Regular assessment of speech perception and speech/language to determine whether the patient meets expected levels of performance and whether performance is stable or improves or declines over time
   4. Regular questioning of the patient and his/her family to determine whether the patient demonstrates any signs suggestive of internal device malfunction
   5. *In vivo* device integrity testing shall be performed in collaboration with the manufacturer
   6. Reprogramming of the device to determine whether performance can be improved
   7. Establishment of a follow-on plan to continue surveillance of device function or explantation and possible revision

10.2 Removal and return of explanted components and analysis report

The manufacturer shall develop a protocol for the removal and return of explanted components for analysis, including subsequent reporting of the analysis results to the clinician and patient.

Key objectives of the protocol shall include the following:

a) Instructions for the proper removal of the device, including precautions to maximize success of re-implantation and minimize further damage to the explanted component because of rough handling, exposure to surgical diathermy, or other factors that could complicate identification of the original failure mode during the follow-on failure analysis. The instructions may include educational material describing the importance of maintaining and protecting the original failed state of the device for accurate failure analysis, such as the text below:
   i. “In order to perform appropriate testing on the device, the entire device including the electrode array should be returned to the device manufacturer, even if it has been severed or damaged during explant. Please return the electrode array, even if it has been disconnected from the implant, and please take special care to minimize the explanted device’s exposure to cautery, mechanical shock, or electrostatic discharge when explanting and preparing the device for return to the manufacturer.”
   ii. “Instructions for the return of the electrode array if severed during explantation. In some cases, the electrode is severed and left in place for future reimplantation surgery, at which time the severed electrode should be retrieved and returned to the manufacturer for analysis.”
b) Provision for the safe and prompt shipment of the explanted components to the manufacturer, employing appropriate biohazard precautions and provisions to prevent further damage to the explanted device.
   NOTE—Manufacturers should ensure that the return process is as easy as possible to ensure compliance by the health care facility. Manufacturers should ensure that explant return kits are readily available at the surgical sites.
c) Collection of descriptive data pertaining to the component and its explantation. At minimum, these data should include the following:
   i. The model number and serial number of the explanted device
   ii. The date of the implant surgery
   iii. The age of the recipient at the implant surgery date
   iv. The date of the explantation surgery
   v. The reason(s) for explantation
d) Collection of information describing the signs and symptoms of the patient leading to explantation of the device. This information should be in the form of a checklist of signs and symptoms provided to the clinician and completed prior to explantation. An example of such a checklist is included in Annex B.
e) Procedures for reporting the results of the device analysis to the clinician and patient. At minimum, these procedures shall include the following:
   i. An initial communication to the clinician that the manufacturer has received the device and a follow-up communication every 90 days thereafter until the failure analysis report is delivered

ii. A failure analysis report written in clear, understandable English (see Annex C for an example of the tests that should be included in such a report) and including the following information:
    1. A statement of the failure classification of the device as per Section 11.2.2
    2. A statement of the root cause of the failure and a description of the factors that contributed to the failure
    3. If no fault was found (either INC or MRE with NFF designation), a statement describing the tests that were performed and the rationale for them. If the electrode array was not returned, a statement must be added that additional testing could not be performed.
    4. A statement(s) about any device observations or failures discovered during the failure analysis process that were unrelated to the root cause
    5. If appropriate, a description of facts and observations which substantiate a surgical error that contributed to the device failure
iii. Provision for sending the failure analysis report to the clinician

Manufacturer shall demonstrate compliance to this section.

10.3 Testing of returned implantable components

Returned implants shall be analyzed to determine the root cause of the reason for return. Manufacturers shall develop protocols to ensure that a systematic process is followed to analyze the returned device and determine the true root cause failure. The root cause failure is the ultimate cause of the failure of the implant. As a minimum requirement, the systematic failure analysis process shall include the steps below to gather information about the failed device. Manufacturers shall establish a standard protocol for medical and non-medical explants (see Annex C for an example). Failure analysis process steps to be followed are listed below.

The non-destructive analysis steps shall be performed on all returned explanted devices (medical and non-medical) and shall be sufficiently comprehensive and rigorous to capture at least 80% of actual device failures. Depending on the results of these tests and the original classification of the complaint or reason for explant, further testing or reclassification of the device might be necessary. Devices that are returned for medical reasons and do not have a patient complaint that might be associated with device operation and that pass steps a) to c) of the non-destructive analysis do not need to undergo all of the steps listed below. (These devices are considered to be Medical Reason – Type A; see 11.2.2.4(d)). Non-medical explants with a failure mode(s) consistent with the observed clinical complaint(s) and not related to the electrical function of the receiver/stimulator, as verified by the results of non-destructive tests (steps a) to c) of the analysis) do not require further testing. If surgical issues are determined to have caused the failure (see 11.2.2.4(d) – Medical Reason – Type C), no further testing is necessary. The remaining steps, including destructive analysis, shall be performed on all remaining non-medical explants and medical explants with potential device-related symptoms (e.g., pain, dizziness). See Section 11 for details. Any step performed, or not performed, or any step performed beyond those listed below shall be justified in sufficient detail in the written report. If a known precipitative event occurred (e.g., impact), the device should be checked for all possible suspected failure modes.

Non-Destructive Analysis

a) Inspection of the implant, including both visual and one other test such as X-ray, electron microscopy, or high- resolution optical microscopy, depending on the nature of the original complaint
b) Basic electrical tests
    i. Link integrity testing, including both forward telemetry and back telemetry if included in device capabilities
    ii. Basic functionality testing, including confirmation of output stimulation
    iii. Simulated clinical testing (shall include saline bath immersion)
c) Inspection of manufacturing records for any anomalies and reliability test data, lot acceptance test data, and screening data, as appropriate
d) Further inspection and testing designed to provide additional information on suspected failure modes determined in a) to c) or as required to explore a patient complaint such as intermittency:
    i. Detailed inspection (can include scanning electron microscopy)
    ii. Advanced tests
        1. Electrical (can include current leakage)
        2. Mechanical (can include temperature cycling, mechanical vibration)
        3. Continuity testing (diagnose for opens, shorts, impedances). The testing shall include saline bath immersion even if the electrode array is not present because this procedure can provide

information about moisture ingressing into the non-hermetic side of feed-throughs. In such cases, a true open or cut array might not manifest as open.

4. Non-destructive hermeticity tests (only if a validated test method is available)

Destructive Analysis

a) Hermeticity tests: Gross leak test shall be performed to verify hermeticity.
b) Residual gas analysis (RGA) testing: Acceptance criteria shall be 5,000 ppm water vapor or a value established by the manufacturer based on engineering analysis and data for each implant model, as described in Section 20.7. This value shall be established to ensure that devices do not fail within the useful life period stated by the manufacturer. The engineering analysis and data for an alternate value shall be included in the information submitted to the regulatory body.
c) Testing with cover removed:
    i. Measurements of receiver-stimulator on electronic assembly pins to commands from external device
    ii. Recordings of waveforms at feed-throughs within specifications in response to test signals
    iii. Detailed inspection of electronic assembly, ASIC for signs of failure such as cracks, moisture leakage path, corrosion products, and manufacturing defects.
d) Determination of failure site and mode on PCB; measurement of specifications of discrete components, including resistors, capacitors, and diodes

NOTE 1—The use of flow charts might assist with the investigation. These flow charts might be design-specific and will need to be updated as knowledge of the various failure modes and their symptoms builds over time. Care should be taken to ensure that the use of a flow chart does not constrain the analysis. The exploration of new failure modes that begins with a hypothesis and follows the scientific method is encouraged.

NOTE 2—Tools such as a design failure modes effects analysis (DFMEA) and process failure modes effects analysis (PFMEA) are useful sources of information that can provide input to the analysis of a failed device. The flow of information should be bidirectional; should new failure modes be found or new information on a new failure mode is gleaned, the DFMEA and PFMEA should be updated. A returned implant is an opportunity to validate the data and assumptions made during the design phase about how the design will perform after years of use *in vivo*. However, the primary focus must be on determining the root cause analysis for the reason for the explant, before any other tests or investigations are performed on the device.

NOTE 3—Other tools such as the “5-Whys” and the “Ishikawa” (fishbone) diagram may also be used to identify all of the possible causes for the failure. It is important that the identification of a solution to the failure is delayed until all of the possible causes have been identified and analyzed.

NOTE 4—An independent review of the results of the analysis by a team of subject matter experts is strongly recommended to avoid the limitation of a single investigator’s “tunnel vision.” Such a team might confirm the analysis or identify additional investigations and possible failure modes that need to be considered.

NOTE 5—It is also important never to completely close an investigation. New information could become available long after the initial analysis was deemed to be complete. This new information needs to be considered and the analysis updated, if relevant.

Manufacturer shall demonstrate compliance to this section.

11 Reliability monitoring and reporting

NOTE 1—This section of the standard describes the procedures, record-keeping, analyses, and documents required for the manufacturer to report device reliability and health-related issues on the basis of the collection and testing of implantable and non-implantable components returned from the field because of suspected failure.

NOTE 2—The requirements of this section are independent of (or in addition to) any reporting requirements established by regulatory bodies.

NOTE 3—See Annex K for a logic flow diagram of the relationships between the required testing, explant category classification, and reliability reporting to both regulatory bodies and the public.

11.1 General requirements

11.1.1 Analysis and recording of field returns

Manufacturers shall analyze returned product and report on the reliability of the product and mechanisms of failure.

Manufacturer shall demonstrate compliance to this section.

11.1.2 Audiences for field reliability information

Among the audiences for field reliability information are employees of the manufacturer and, under confidentiality agreements, other parties such as regulators. All reliability information reported to regulatory bodies in accordance with Section 11.4 shall be marked as confidential.

In addition, the public, including potential and existing cochlear implant recipients and parents in the case of pediatric recipients, and the clinical community have an interest in this information. Consequently, Section 11.5 stipulates requirements for public disclosure of summary information regarding the field reliability of implantable and external components.

Manufacturer shall demonstrate compliance to this section.

11.1.3 Components for which reliability reporting applies

11.1.3.1 Implantable components

Reliability measures are based on examination of implantable components that have been explanted and returned to the manufacturer.

Reliability regarding medical and non-medical device issues shall be reported to regulatory bodies for all implantable components beginning after the first implant following receipt of FDA marketing authorization (device approval given by FDA). The first report shall contain reliability data beginning with the date of the first commercial global implant. The total reportable census shall be for implantable components sold globally for as long as any devices remain implanted. Reporting shall continue for 20 years after the last implantation of that device type in the United States. The schedule and method of regulatory reporting is specified in Section 11.4.1.

Reliability shall be reported to the public for all implantable components starting when the global *in vivo* census reaches 500, or no later than twelve months after the first implant (whichever comes first). Public reporting for a particular component shall continue for 20 years after the last implantation of that device type in the United States. The total reportable census shall be for implantable components sold globally for as long as any devices remain implanted. The schedule and method of public reporting is specified in Section 11.5.1.

Implants returned without being implanted, including out-of-box failures or those that were *in vivo* and were determined to be ineffective before closure of the surgical incision, are not included in the reporting; otherwise, all explanted devices shall be included in the analysis and reporting.

Manufacturer shall demonstrate compliance to this section.

11.1.3.2 Non-implantable components

Reliability shall be reported only for sound processors, for all models that are currently commercially marketed in the United States. Reporting to regulatory bodies will begin with the first device sold, whereas reporting to the public will begin starting when sales have reached 500, including back-up components, or no later than twelve months after the first unit is shipped (whichever comes first). Reporting shall continue for each device model until it is no longer sold by the manufacturer in the United States. In the event of patient death or loss of the equipment, the non-implantable components shall be removed from the total reportable census.

Returns related to other components and consumable items (e.g., headpieces, remote controls, microphones, microphone covers, cables, and batteries) or preventive maintenance (e.g., a user or manufacturer replaces a consumable or upgrades fully functional components) are excluded from the data and hence are not reported.

This requirement applies for reporting to both regulatory bodies and the public.

Manufacturer shall demonstrate compliance to this section.

11.1.4 Registration of implantable components and notification of their explantation or removal from service

Registration of cochlear implant systems is important in ensuring the accurate recording of data necessary for the reporting of device reliability and the ability of the manufacturer to follow up with the patient. Best practices dictate that the clinician promptly complete the device registration forms and provide the information to the manufacturer. In the event that the clinician becomes aware that an implanted patient has passed away for any reason, he or she shall notify the manufacturer so that the patient implant status can be updated.

The manufacturer shall provide means for the clinician to register implantable components with the manufacturer following implantation surgery. The registration information shall include identifying information for the patient (e.g., name or other identification, date of birth), center and device (e.g., model number, serial number) and date and ear of implantation. Simultaneously implanted bilateral devices shall be registered separately.

The manufacturer shall provide a means for clinicians to notify the manufacturer of the explantation or removal from service of implantable components and to provide relevant information about the specific device, the condition of the patient, and the circumstances leading to explantation or removal from service. Minimum reporting requirements and procedures for return of the explanted component for failure analysis are specified in Section 10.2.

If an unregistered implantable component is returned, the manufacturer shall

a) inform the clinic of the correct registration requirements,
b) request the relevant missing information from the clinic, and
c) correct the reliability field reporting calculations by adjusting the total number at risk.

In the event of missing data, the manufacturer shall make best efforts to obtain the data. If unsuccessful, then the shipping date shall be used as the date of implantation. Manufacturers shall make their best effort to ensure that all explanted devices are returned to the manufacturer for analysis. Best practices dictate that clinicians ensure that all explanted devices are returned to the manufacturer for analysis along with supporting data to facilitate the analysis.

Manufacturer shall demonstrate compliance to this section.

11.1.5 Complementary field data describing the history of the system in the field

To assist in root cause failure analysis, manufacturers shall establish procedures to obtain data from clinicians regarding the reasons for explantation (see Section 10.2).

When possible, symptoms identified prior to explantation, which were observed and/or reported by the clinician, patient, parent, or caregiver, shall be documented and categorized by the manufacturer by failure mechanism, if known. Such information shall be used to refine the guidelines and procedures required by Sections 10.2 and 11.1.6.

Manufacturer shall demonstrate compliance to this section.

11.1.6 Requirements for field assessment of implantable components suspected of failure

In order to minimize erroneous explantations, manufacturers shall create guidelines, tools, and recommendations to enable an informed diagnostic process prior to explantation. These diagnostic procedures should be in keeping with the technology of the device and may include, but are not limited to, the following:

a) *In vivo* device integrity testing (see Section 10.1)
b) Impedance measurement and programming history
c) Assessment of signs and symptoms experienced by the patient
d) Objective hearing tests
e) Subjective hearing sensitivity, speech/language, and speech perception tests
f) Guidelines for verification of component placement using imaging

Information regarding the availability of this material shall be included in the device labeling (Section 12.21).

Manufacturer shall demonstrate compliance to this section.

11.2 Specific requirements related to implantable components

11.2.1 Identification and documentation of failed implantable components

Records on failed implants shall include data on the following:

a) Product identification details
   i. Model number
   ii. Serial number
   iii. Date of manufacture
   iv. Implant life (date of explantation minus the date of implantation in years). If the date of implantation is unavailable, the shipping date shall be used as the date of implantation.
   v. Date of first reporting of problem(s) leading to explantation
   vi. Date of explantation
b) Patient details
   i. Patient age at time of implantation
   ii. Reason for explantation (medical vs. nonmedical)
   iii. In the case of medical reasons, a description of the specific medical reason, in accordance with the classification in Section 11.2.2
   iv. Indications of performance decline (see Annex D)
   v. Special events during implant life that might have affected the results (e.g., head trauma, meningitis, changes in patient's general health)
c) Root cause failure analysis
   i. The results of *in vivo* testing as specified in Section 10.1
   ii. The results of *ex vivo* testing as specified in Section 10.3
   iii. A statement about the primary failure mechanism, if known

   NOTE—This information is based on the classification determined in accordance with Section 11.2.2. The primary failure mechanism is the root cause condition that initiated failure and that will be used in the reliability report to regulatory bodies in accordance with Section 11.4 and to the public in accordance with Section 11.5.

d) A statement about observations that led to the determination of the root cause as well as observations or other findings that were unrelated to the root cause shall be included in the report.

   NOTE—An example of other unrelated failure mechanisms would be observed hermeticity leakage and resulting electronic failure, other than the primary condition of physical damage to a feed-through component.

Manufacturer shall demonstrate compliance to this section.

11.2.2 Analysis and classification of explanted components

11.2.2.1 General requirement

Explanted components shall be analyzed and classified by the manufacturer.

The analysis and classification procedures for identifying and describing device failure shall meet the minimum requirements described in the following subsections. The manufacturer shall document the analysis and classification process for each explanted device examined.

Manufacturer shall demonstrate compliance to this section.

11.2.2.2 General process for analysis of explanted components

In general, the examination of returned, explanted components is a continuing process of identifying failed devices and documenting the associated failure mode and failure mechanism. This process includes decontamination and initial functional testing of individual returned items (Section 11.2.2.3), followed by classification of each unit on the basis of a review of test results and of the clinical history leading to explantation (Section 11.2.2.4).

At minimum, the explant review process shall follow the requirements in Section 10.3. The minimum procedures and classifications for failure analysis of implantable components are summarized in Figure 9 and Table 7, respectively.

At least 80% of the explant failures should be captured in the failure modes listed in Table 7, excluding the “Other” or “Unknown Mechanism” categories. For explant failures where the failure mode is known but is not included in the list of known failure modes, then the manufacturer shall define the new failure mode to capture these failures. The next reliability report submitted to the regulatory body (Section 11.4) shall include a clear and concise description of the new failure mode, along with a rationale for why the failure modes listed in Table 7 were not appropriate. This requirement is to avoid the situation where 20% or more of the failure modes are listed as “Other” or “Unknown.”

At periodic calendar intervals, the return analysis findings shall be reported in summary reliability reports to regulatory bodies and the public (see Sections 11.4 and 11.5).

Manufacturer shall demonstrate compliance to this section.

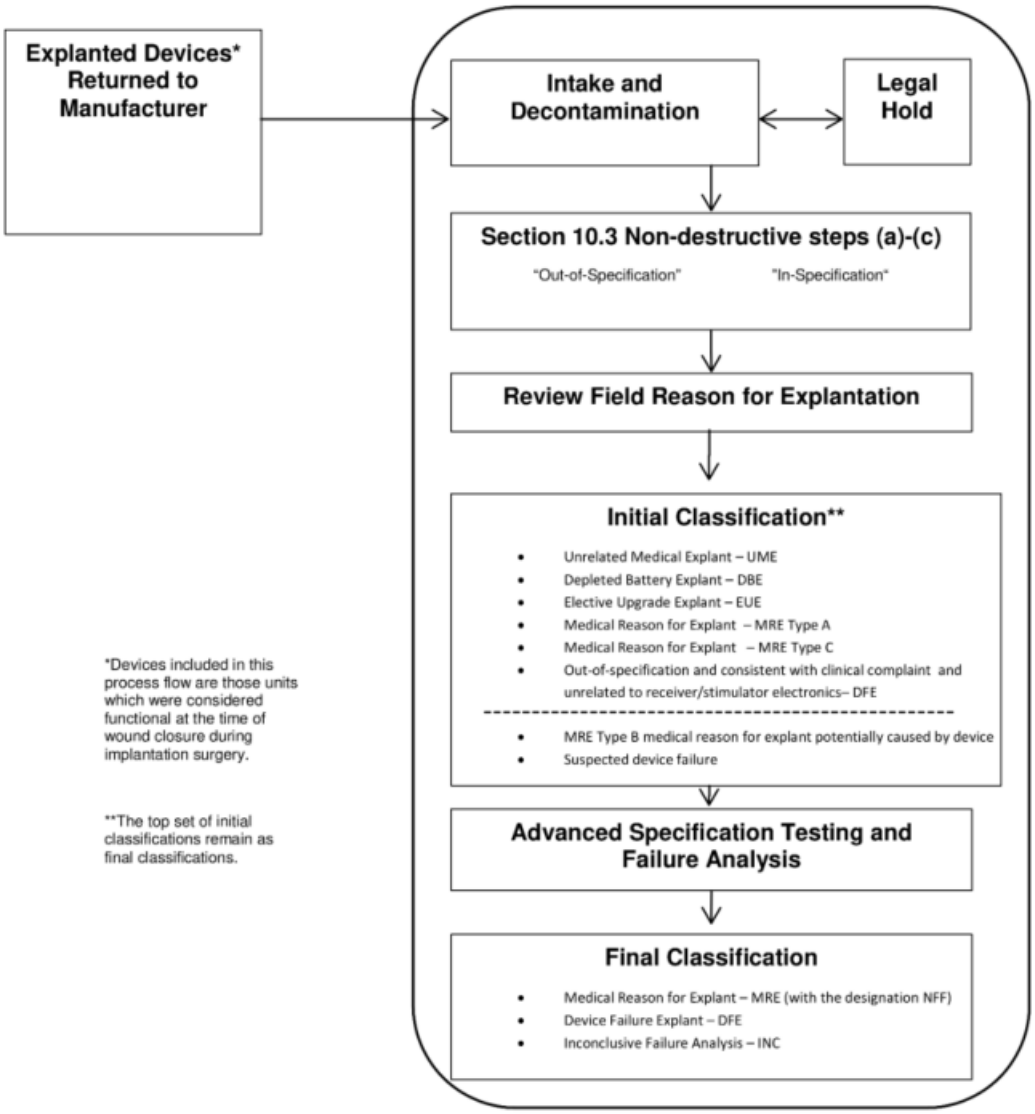


Figure 9—Minimum procedures for failure analysis of implantable components

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Table 7- Classifications of explanted devices

Categories <u>not included</u> in Reliability Reporting

- **Unrelated Medical Explants – UME** (Functional; device explanted for medical or therapeutic reasons)
- **Depleted Battery within designed time window – DBE** (Functional)
- **Elective Upgrade Explant – EUE** (Functional; see Section 11.2.2.4 for details)

Categories <u>included</u> in Reliability Reporting

- **Explanted for Medical Reason – MRE**
  - <u>MRE Type A</u> (In Specification)
    Must pass Section 10.3 Non-Destructive Analysis steps a) to c).
    - Infection
    - CSF Leakage
    - Meningitis
    - Skin Flap Complication
    - Misplaced Electrode Array
    - Electrode Migration
    - Implant Migration/Extrusion
    - Other
  - <u>MRE Type B</u> (initial classification is DFE)
    Must pass all tests in Section 10.3 to be classified as MRE with the designation of NFF (No Fault Found) with explant cause.
    - Pain/Burning
    - Dizziness
    - Anomalous Percepts
    - Performance Issues
    - Extracochlear Stimulation
    - Other
  - <u>MRE Type C: Surgical Error</u> – Device Damage (initial classification is DFE)
    The device failed at least one test in Section 10.3 and upon investigation it was determined that an event occurred during implant surgery that initiated the device failure.
- **Device Failure Explants – DFE** (Out of Specification)
  - Electronic Component/Assembly
  - Electrode/Electrode Lead
  - Receiver Coil
  - Magnet Issue
  - Excess Moisture in the Device
  - Case Damage
  - Feed-Through Damage
  - Implantable Battery Failure
  - Obsolescence (Unsupported Device)
  - Manufacturing Process Error
  - Other (Specify)
  - Unknown Mechanism
- **INC (Inconclusive)** (In Specification – must pass all tests in Section 10.3)

Total Explants = UME + DBE + EUE + MRE + DFE + INC

11.2.2.3 Intake, decontamination and initial functional screening

Intake and decontamination are at a minimum parts of a triage stage during which the device is received from the field and logged into the manufacturer's return analysis system. Unless the device is on Legal Hold, all returned explanted devices shall undergo the non-destructive analysis, steps a) to c), of Section 10.3. If the device is on Legal Hold, a determination is made as to whether analysis should proceed, pending clearance of legal issues. Legal Hold may be invoked at any point in the testing and analysis process as legal circumstances dictate, at which point the status of the device is preserved pending resolution of the legal issues. If testing may proceed, the device is visually examined to document the device's return state and then decontaminated for additional examination.

Follow-on examination may include X-ray scanning, photographic documentation, activation of the device under laboratory conditions to determine its functional state to the extent possible (beyond the required Section 10.3 non-destructive test b)(iii)), and any other testing the manufacturer deems appropriate, given the condition of the device (e.g., physical damage to the case, a cut or sliced lead, or a missing electrode array). In general, any destructive testing of the component is avoided during the initial assessment. During this preliminary stage, documentation is also gathered from the clinic, including clinical reports of the history and the patient signs and symptoms leading to explantation. Appropriate device fitting and electrode impedance files are also obtained from the field clinic, if indicated. After the initial screening is completed and the relevant documents are gathered, the device is ready for initial classification.

11.2.2.4 Classification of explanted components and full specification testing

The process specified in Section 10.3 shall be followed for all explanted devices. The general procedure is summarized in Figure 9. Based on a review of the initial analysis of the returned device (i.e., non-destructive analysis steps a) to c) of Section 10.3) and of the medical history leading to explantation, the device is initially classified based on one of five general reasons for explantation. These reasons include the following:

a) Explantation due to unrelated medical reasons
b) Explantation due to a depleted battery within expected design specifications
c) Explantation due to elective upgrade
d) Explantation due to medical reasons directly related to the cochlear implantation
e) Explantation because of suspected device failure

Devices found to be in-specification as determined by the non-destructive analysis steps a) to c) of Section 10.3 that all explants undergo and explanted for one of the reasons a) to d) as listed immediately above are assigned to categories UME, DBE, EUE, or MRE, respectively. These categories are further defined below. Fully implantable functional devices with batteries that depleted outside of design specifications are considered to be devices with suspected failure and are routed into further testing and failure analysis for final classification. All devices found to be out-of-specification per the non-destructive analysis steps a) to c) of Section 10.3 are DFE devices. Those DFE devices that might be due to electronic receiver/stimulator failure shall be further tested using advanced specification testing and failure analysis. Those devices explanted because of suspected device failure but found to be in-specification per the non-destructive analysis steps a) to c) of Section 10.3 shall be further tested using advanced specification testing and failure analysis for assignment to categories DFE, INC, or MRE (with designation NFF), depending on the results of the tests.

As shown in Table 7, the final classification categories are defined as follows:

a) **Category UME: Explantation because of unrelated medical reasons – Non-failure**. This category applies to returned units explanted for medical reasons unrelated to the functioning of the devices. Examples of devices qualifying for this category are those removed to facilitate/enable diagnostic or therapeutic medical procedures for conditions unrelated to the implantation or function of the device (e.g., MRI scanning needs outside of the manufacturer's specification, radiotherapy, surgical resection).

   To qualify for this category, the unrelated medical reason for explantation must be documented. If returned, the device must pass the required functional testing of non-destructive analysis steps a) to c) of Section 10.3. The clinical history, including patient complaints, patient auditory performance, and device performance (e.g., changes in impedances or number of active electrodes), shall also be considered, as applicable, for exclusion from this category and inclusion as a suspected device failure.

b) **Category DBE: Planned explantation because of depletion of implantable battery – Non-failure**. This category applies to returned units explanted because of depletion or end of life of the implantable battery (primary or other). If the operational time of the device to battery termination is earlier than the design specification of the device, the device shall be assigned to the DFE category and a full analysis shall be performed. To qualify for the DBE category, the device must be determined to be otherwise in specification, including compliance with the requirements of Section 20.2 during subsequent testing with substitute power; otherwise, the device shall be classified as DFE. The returned device must pass the required functional testing of non-destructive analysis steps a) to c) of Section 10.3; otherwise, the device shall be classified as DFE.

NOTE—This section applies to future designs; currently, there are no known devices with implantable batteries.

c) **Category EUE: Planned explantation because of elective upgrade – Non-failure**. This category applies if the patient elects to upgrade, provided that the manufacturer still fully supports the existing implant model and its external accessories and allows the latest approved external devices to be used with the implant. Explantation is elected because a technology upgrade exists to allow an expected hearing benefit for the patient.

To qualify for this category, the original implanted device, including electrode, must be within specification. The replacement device must contain upgraded functionality compared to the in-situ device. The clinical reason for explantation must be documented and indicate that there is an expected benefit from the new technology. The returned device must pass the required functional testing of non-destructive analysis steps a) to c) of Section 10.3.

The clinical history, including patient complaints, a decrease in patient auditory performance, and any change in device performance (e.g., significant changes in impedances or number of active electrodes), shall be considered, as applicable, for exclusion from the category of Elective Upgrade and inclusion as a suspected device failure.

NOTE—This category does not apply to devices suspected of performance issues for which the appropriate category is either DFE or INC, depending on the results of device analysis.

d) **Category MRE: Medical reason for explants**. This category applies to returned units explanted for medical reasons related to the implantation or functioning of the device. For each device, the manufacturer shall describe the medical failure mode that is the basis for this classification according to the clinical reports. MRE devices shall be considered failed for reliability reporting purposes. To qualify for this category, the device must be determined to be functional (see Section 10.3 non-destructive analysis steps a) to c)); otherwise, the device shall be classified as DFE.

MRE Type A devices are specified below.

MRE Type B devices are devices explanted from patients with medical symptoms that could be caused by device malfunction and that could occur more reliably when the device is powered versus not powered (e.g., pain, burning, anomalous percepts, facial nerve stimulation, performance decline). Such devices shall be initially assigned to the DFE category for detailed testing per Section 10.3, including destructive analysis testing, and may be later reassigned to the MRE category with the designation of NFF if the device is found to be in specification.

MRE Type C devices are devices explanted from patients with clinical complaints that could be caused by device malfunction. Such devices shall be initially assigned to the DFE category for testing per Section 10.3 a) to c). If the failure analysis concludes that the damage was caused by surgical error, off-label use, or failure to adhere to device labeling, these devices may be later reassigned to the MRE Type C category.

Specific reportable failure modes for the MRE category are defined as follows:

MRE Type A (must pass Section 10.3 Non-destructive analysis steps a) to c) in order to be classified as MRE)

i. *Meningitis:* Explantation due to occurrence of meningitis secondary to cochlear implantation

ii. *Infection:* Explantation due to occurrence of infection in the vicinity of the stimulator, lead, and/or electrodes
iii. *Cerebrospinal fluid (CSF) leakage:* Explantation due to occurrence of CSF leakage secondary to cochlear implantation
iv. *Skin flap complications:* Explantation due to occurrence of skin flap complications secondary to cochlear implantation
v. *Misplaced electrode array:* Explantation due to misplacement of electrode array during cochlear implantation
vi. *Electrode migration:* Explantation due to migration of the electrode array out of the cochlea
vii. *Implant migration/extrusion:* Explantation due to medical complications secondary to migration or extrusion of the implant device or lead
viii. *Other (specify):* Explantation when the primary cause for removal was the patient experiencing another medical reason not listed above. The specific sign or symptom or other reason shall be described in the report to the regulatory body.

MRE Type B (must pass all test specified in Section 10.3 to be classified as MRE, with the designation of NFF)

i. *Pain/burning:* Explantation due to occurrence of pain secondary to cochlear implantation
ii. *Dizziness:* Explantation due to occurrence of balance and other vestibular-related issues secondary to cochlear implantation
iii. *Anomalous percept:* Explantation due to occurrence of sounds such as distortion, static, crackling, or popping
iv. *Performance issue:* Explantation because the patient experienced a performance decline or failed to achieve a clinically expected performance level attributable to health-related issues. Explantation due to performance decline because of loss of functional electrode channels shall be classified in the DFE category according to the identified failure mode (e.g., electrode failure, lead failure, electronic failure). If the manufacturer determines that the performance decline is not related to the electrode channels, the rationale shall be documented in the failure analysis report for the explanted device.
v. *Extracochlear stimulation:* Explantation due to occurrence of stimulation at sites outside of the cochlea (e.g., facial nerve, middle ear [Jacobson's Nerve], chorda tympani, return electrode location) secondary to cochlear implantation and resulting from medically related factors (e.g., anatomical malformation, otosclerosis).
vi. *Other (specify):* Explantation when the primary cause for removal was the patient experiencing a sign or symptom not listed above. The specific sign, symptom, or other reason shall be described in the report to the regulatory body.

MRE Type C (must pass Section 10.3 Non-destructive analysis steps a) to c) in order to be classified as MRE)

i. *Surgical related explants:* Explantation due to surgical error, off-label use, or failure to adhere to device labeling

e) **Category DFE: Device failure explants**: This category applies to returned units explanted because of confirmed malfunctions, as determined either by analysis of the returned product or by *in vivo testing*. Returned product analysis results supersede *in vivo* testing results. If the device is determined to be out of specification, failure analyses shall be conducted and specific failure mechanisms shall be assigned to each DFE device per the listing shown in Table 7. If the "other" category is selected, the specific mechanism shall be described. If the "unknown" category is selected, an explanation shall be provided. DFE devices shall be considered failed for reliability reporting purposes. If the manufacturer identifies multiple causes for device malfunction and subsequent explantation, the primary failure determined by the manufacturer to be most directly responsible for the clinical explantation shall be reported in the statistical analysis (see (c), iii, in Section 11.2.1). The remaining non-primary failures shall be described in the documentation as other failures for the specific device under analysis [see (d) in Section 11.2.1].

Specific reportable failure modes for the DFE category are defined as follows:

i. *Electronic component/assembly:* Explantation due to documented failure of an electronic component(s) and/or assembly.

ii. *Electrode/electrode lead:* Explantation due to shorts, opens, or other material or electrical failures of the electrode array or lead. Damage due to either incorrect surgical handling or off-label use would be considered a medical issue and reclassified as a MRE Type C (Surgical related explant), but only if the damage clearly occurred prior to explantation.

iii. *Receiver coil:* Explantation due to mechanical, electrical, or material failures of the receiver coil. Damage due to either incorrect surgical handling or off-label use would be considered a medical issue and reclassified as a MRE Type C (Surgical related explant), but only if the damage clearly occurred prior to explantation.

iv. *Magnet issue:* Explantation due to documented failure or out-of-specification function of the implantable magnet assembly.

v. *Excess moisture in the device:* Explantation due to device failure caused by excessive water vapor levels that impact the performance of the device. Excessive water vapor levels could be due to various mechanisms (e.g., ingress due to loss of hermeticity, vulnerability to ingress built in because of the manufacturing process). In cases where there is gross physical damage to the case or feed-through system, the explant should be assigned in those specific classifications (see vi and vii below).

vi. *Case damage:* Explantation due to device failure secondary to documented case damage.

vii. *Feed-through damage:* Explantation in cases where there is gross physical damage to the feed-through system. In such cases, device failure is likely due to the loss of hermeticity; however, the failure mode is identified as the physical damage.

viii. *Implantable battery failure:* Explantation is due to depletion of an implantable battery outside of design specifications, primarily because of a failure of the battery itself.

ix. *Obsolescence:* Implants that are returned because the patient elects to upgrade because the manufacturer no longer fully supports this implant model and its external accessories.

x. *Manufacturing process error:* Explantation due to an error that occurred during manufacturing that leads to the device failure (e.g., improper welding parameters that lead to loss of hermeticity)

xi. *Other (specify):* Explantation of a DFE device where the primary cause of a device failure mode is not listed above. The specific failure mode shall be described in the report to the regulatory body.

xii. *Unknown mechanism:* Explantation of a DFE device where the primary cause of the device's out-of-specification function is unknown following full failure analysis. The current status of the investigation shall be described in the report to the regulatory body. This classification may be changed as additional information and insight become available. This category does not apply to devices in ongoing analysis.

f) **Category INC: Inconclusive Failure Analysis**. This category applies to those explanted units that have failed *in vivo* testing but are determined to be within the manufacturer's specification using the method described in Section 10.3. For a device to be classified into the INC category, a full failure analysis must have been completed, including hermeticity and residual gas testing as described in Section 10.3. INC devices shall be reported as a separate category along with MRE and DFE for reliability reporting purposes.

Should new insight into or knowledge about possible failure mechanisms become available, the manufacturer shall review previous device classifications where the information might apply and adjust the classification and reliability reporting at the next scheduled reporting interval. If an adjustment is made, the reports shall include an explanation of the change.

Manufacturer shall demonstrate compliance to this section.

11.3 Specific requirements related to non-implantable components

11.3.1 Testing of returned non-implantable components

The manufacturer shall implement a returned-device analysis process for sound processors only.

Screening processes including sampling techniques and sampling statistics may be used, provided that the confidence intervals (90%, two-sided) are shown in the report.

Manufacturer shall demonstrate compliance to this section.

11.3.2 Identification and categorization of returned non-implantable components

For sound processors, identified failure modes or symptoms (observed and/or reported by the clinician, patient, parent, or caregiver) shall be documented and categorized by failure mechanism, if known. Reliability metrics shall be recorded at least for the United States population. These metrics are applicable to serialized devices only.

The returned sound processors shall be tested and categorized, at minimum, as follows:

a) Out-of-specification processors are classified in one of four categories.
   i. *Mechanical:* A functional failure resulting from physical damage caused by mechanical stress, chemical exposure, or ultraviolet (UV) exposure that is a result of normal use. This category excludes normal wear and tear and cosmetic damage, provided that the device is still functional. Failure of switches and connectors within the warranty period should be included in this category.
   ii. *Electronic:* A functional failure of the electronics or the electronic assembly
   iii. *Moisture damage*: A functional failure that is a result of moisture ingress. This category excludes corrosion and other similar damage unless it results in a functional failure.
   iv. *Other (specify)*: Failures that don't fit in the above categories (e.g., firmware failures)

b) In-specification processors are classified as fault-free (FF).

A returned device that is fully functional in accordance with Section 8.7 shall be classified as fault-free. The component's condition might reflect cosmetic and other damage because of normal wear and tear, such as minor mechanical damage (including scratches, cracks, and discoloration), corrosion, and moisture damage that did not result in a functional failure.

Fully functional components returned for upgrade (e.g., model change, color change) shall not be included in the analysis.

Figure 10 shows this categorization in schematic form.

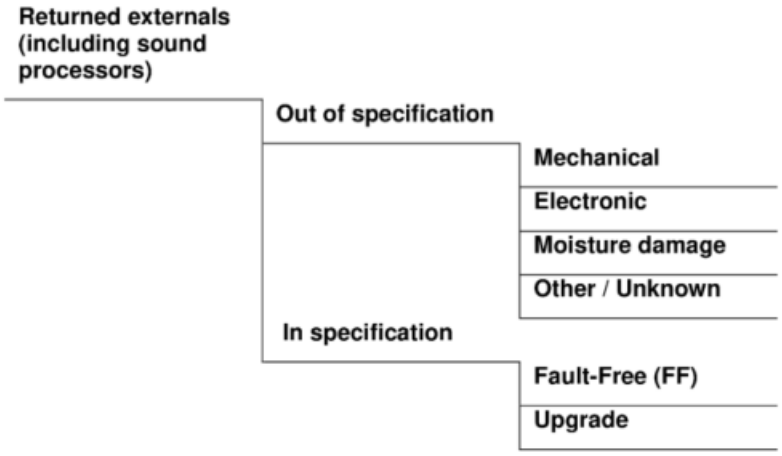


Figure 10—Minimum classifications for failure analysis of sound processors

Reporting requirements for these data are described in Section 11.4 for regulatory bodies and in Section 11.5 for the public and clinical communities.

Manufacturer shall demonstrate compliance to this section.

11.4 Requirements for reporting field reliability data to regulatory bodies

NOTE—The reliability of a CI system is a key consideration for regulatory authorities. This section defines a standardized and detailed method and format for regulatory reporting of the reliability of a CI system based on actual field data in accordance with eligibility, as defined in Section 11.1.3.

11.4.1 Schedule and method of reporting to regulatory bodies

The manufacturer shall provide confidential, proprietary reliability reports to regulatory entities on a semiannual basis for the implantable and external components (defined in Sections 11.4.2 and 11.4.3). The reports shall be provided at the end of the first and third quarters of the calendar year and include the data collected through the end of the fourth quarter of the previous calendar year or the second quarter of the current year, respectively. The reports shall include data for components for which the failure analysis has been completed (see Sections 11.2 and 11.3). Data for components still undergoing analysis at the end of the current reporting interval shall be reported in the subsequent report. On average, failure analysis shall be completed within one quarter of a year from the receipt of the component.

Manufacturer shall demonstrate compliance to this section.

11.4.2 Implantable components reliability report to regulatory bodies

11.4.2.1 General requirement

The field performance of the implanted components of a cochlear implant system shall be reported to regulatory bodies in the following forms (see Annex E):

a) Data and analysis of cumulative failure percentage (CFP) (Section 11.4.2.2)
b) Pareto analysis of primary root cause of failure mechanisms (Section 11.4.2.3)

Global field data shall be reported for the following combinations of implantable components sold in the United States:

a) The aggregate summation of all component combinations for each type of receiver–stimulator system (see Section 5.2.1.1) being used as a common element. These component combinations shall be named according to the commercial product designation of the dominant receiver–stimulator system.
b) The aggregate summation of all component combinations for each type of electrode system (see Section 5.2.1.2) being used as a common element. These component combinations shall be named according to the commercial product designation of the dominant electrode system.

The report shall include an implantable system configuration table that describes for each component combination the constituent parts, the commercial product model designation(s) employing the configuration, and the percentage distribution of field use of each individual configuration in the U.S.

In the event that the manufacturer makes a substantial design, process, or reliability improvement, the manufacturer shall ensure that the reporting describes the change and treats components affected by the change as new components so that the reliability performance can be observed separately.

Manufacturer shall demonstrate compliance to this section.

11.4.2.2 Analysis of cumulative failure percentage

For each aggregate summation of all component combinations for each type of receiver–stimulator system and for each type of electrode system as described in 11.4.2.1, an actuarial analysis shall be performed. The cumulative failure percentage (CFP) shall be reported as a function of an integer number of three-month and 12 month analysis intervals since implantation. Model designations shall be consistent with the models described in Sections 5.1 and 5.2.

For the purposes of this standard and to ensure consistent analysis intervals, twelve months shall equal 365.25 days and three months shall equal 91.3125 (365.25/4) days.

The CFP calculation may be updated as new data become available.

Failures for pediatric and adult patients shall be reported separately and combined, as follows:

a) Pediatric patients <10 years old at the time of implantation
b) Patients ≥10 years old at the time of implantation (denoted as “adults” in this document)

c) All patients taken together

Due to privacy laws in certain countries, recipient personal information might not be obtainable. Under such circumstances, the relevant device should be treated and reported as belonging to an adult. Although it is acknowledged that treating patients with unknown age as adults will likely bias the data, the practice is recommended so that the device explantation is recorded and will be included in statistics for all ages. It is also expected that the occurrence of this practice will be infrequent and that the bias will be small. If the manufacturer determines that there is a high likelihood of bias in the reported data, the report should state this information.

The CFP is calculated by first computing the cumulative survival probability using the general analysis methods described in ISO 5841-2. Measured variables are based on the status of devices during an analysis interval defined from the beginning of the interval, t_0, to the end of the interval, t_e. The analysis interval shall be three months in duration. The first analysis interval for a given device begins at wound closure during implantation. Subsequent analysis intervals of equal duration follow on sequentially throughout the life of the device.

NOTE: ISO 5841-2 is not normative for this standard, but is mentioned because it is the example on which the following requirements are based. The requirements for reliability reporting for this standard are fully specified within this standard itself.

Analysis variables are defined as follows:

N(t): The number of units in service at the beginning, t_0, of any given analysis interval

A(t): The number of units in service whose implant duration, calculated at the end of the analysis period, falls within the interval, t_o to t_e

L(t): The number of units lost to follow-up during the analysis interval. Units could remain permanently or temporarily lost to follow-up. Examples include the following:

- Units still implanted in patients unwilling to continue standard follow-up care for cochlear implants
- Units still implanted in patients but not in service because of clinical guidance or patient choice
- Units explanted but physically lost and not returned to the manufacturer

D(t): The number of units removed from service because of patient deaths during the analysis interval. The deaths, as far as can be verified, shall be unrelated to the implantation or functioning of the device. The unit count in this category shall be based on the actual device count per unilateral or bilateral implantation in each patient and not on the number of patient deaths. Manufacturers are not required to seek return of devices in cases of unrelated death, in order to respect the wishes of the recipient or family or to enable temporal bone donations by recipients. If a death is related to the device, then the explant shall be classified as either DFE or MRE, as applicable.

UME(t): The number of explanted units classified as Unrelated Medical Explant (UME) during the analysis interval (see Section 11.2.2.4)

DBE(t): The number of explanted units classified as Depleted battery Explant (DBE) during the analysis interval (see Section 11.2.2.4)

EUE(t): The number of units classified as Elective Upgrade Explant (EUE) during the analysis interval (see Section 11.2.2.4)

MRE(t): The number of explanted units classified as Medical Related Explant (MRE) during the analysis interval. These devices include MRE Type A, MRE Type C, and MRE with NFF designation devices (see section 11.2.2.4).

DFE(t): The number of explanted units classified as Device Failure Explant (DFE) during the analysis interval (see Section 11.2.2.4)

INC(t): The number of explanted units classified as Inconclusive Failure Analysis (INC) during the analysis interval (see Section 11.2.2.4)

OA(t): Units that were received during the interval, but whose return analysis is not completed by the end of the interval. These units shall be reported as Open Analysis.

E(t): The total number of units explanted within the analysis interval and meeting any of the following criteria:

a) Unit was in-specification and was explanted for unrelated medical reasons (UME).
b) Unit was explanted because of implantable battery depletion within design specifications (DBE).
c) Unit's return analysis has not been completed (OA).
d) Unit was lost to follow-up (L).
e) Unit was explanted for elective upgrade reason (EUE).

C(t): The total number of units explanted for product- or implantation-related reasons during the analysis interval.

The cumulative survival percentage (CSP) and cumulative failure percentage (CFP) are calculated as follows:

The number of units explanted in specification or lost to follow-up within the interval [E(t)]:

$$\boldsymbol{E(t) = UME(t) + L(t) + DBE(t) + EUE(t) + OA(t)} \quad \textbf{(1)}$$

The total number of units explanted for product or implantation-related reasons during the analysis interval [C(t)]:

$$\boldsymbol{C(t) = MRE(t) + DFE(t) + INC(t)} \quad \textbf{(2)}$$

The units at risk [U(t)] (the effective number of units in service that are subject to a change in category during the interval):

$$\boldsymbol{U(t) = N(t) - \frac{A(t)+D(t)+E(t)}{2}} \quad \textbf{(3)}$$

The survival fraction [P(t)] (the estimated probability that a unit entering the interval will operate normally to the end of the given interval):

$$\boldsymbol{P(t) = 1 - \frac{C(t)}{U(t)}} \quad \textbf{(4)}$$

The cumulative survival [S(t)] (the estimated probability of a unit surviving from the time of implant to the end of the given interval, the product of the survival fractions):

$$\boldsymbol{S(t) = P(t) * P(t-1) * \ldots . * P(1)} \quad \textbf{(5)}$$

The survival time for each device begins with closure of the wound after surgical placement of the CI device.

The cumulative survival percentage [CSP(t)] (the cumulative survival probability expressed as a percentage):

$$\boldsymbol{CSP(t) = 100 * S(t)} \quad \textbf{(6)}$$

The cumulative failure percentage [CFP(t)] (the cumulative failure percentage based on CSP(t)):

$$\boldsymbol{CFP(t) = 100 - CSP(t)} \quad \textbf{(7)}$$

The CFP shall be calculated to two decimal points.

The confidence intervals for the CFP shall be calculated according to the Greenwood method (Greenwood, 1926).

The CFP data shall be presented in a graphical format with the following characteristics:

a) Confidence intervals (95%, two-sided) shall be shown for CFP using error bars (90%, if the population is less than 1,000). The error bar characteristics shall be stated in the graph.
b) The horizontal axis shows usage time in an integer number of three-month analysis intervals.
c) The vertical axis shows CFP as a percentage.
d) The CFP is the total of the explant categories, including MRE, DFE, and INC, which shall also be plotted.

e) The CFP data for the adult and pediatric subgroups, in addition to the aggregate data, shall be reported in different graphics.
f) The CFP data shall also be reported using an integer number of 12-month analysis intervals using the associated threshold for public reporting (Section 11.1.3.1).

An example graphic is shown in Annex E. For brevity, the graphs shown in Annex E only use 12-month analysis intervals and represent the limited publicly reported data (Section 11.5.2). However, for compliance to this standard, data shall also be analyzed and graphed using three-month analysis intervals and 12-month analysis intervals, consistent with the requirements stated above.

The CFP and the contributing data categories of MRE, DFE, and INC, as well as N (number of units in service at the beginning of each analysis interval) and the other contributing data to U (units at risk) shall also be presented in a tabular format in a digital (electronic) file with the following characteristics:

a) Confidence intervals (95%, two-sided) shall be presented for CFP (90%, if the population is less than 1,000). The confidence interval characteristics shall be stated in the table.
b) The columns in the table each represent analysis intervals, each three months in duration, with the CFP for each interval shown as a percentage.
c) For each of the analyzed patient populations (all patients, patients ≥10 years old, and patients <10 years old), separate rows in the table shall be represented as N, A, D, OA, L, DBE, EUE, UME, MRE, DFE, INC, CFP_{MRE}, upper confidence interval for CFP_{MRE}, lower confidence interval for CFP_{MRE}, CFP_{DFE}, upper confidence interval for CFP_{DFE} , lower confidence interval for CFP_{DFE}, CFP_{INC}, upper confidence interval for CFP_{INC}, lower confidence interval for CFP_{INC}, CFP_{TOT}, upper confidence interval for CFP_{TOT}, and lower confidence interval for CFP_{TOT}. The individual CFP data and the associated confidence interval data shall be reported to at least two decimal places. The remaining data shall be reported as integers.
d) A second table shall be provided using 12-month analysis intervals to match the publicly reported data in Section 11.5.2.

An example table of CFP variables to be reported is shown in Annex E.

The report shall state that it has been prepared in accordance with this part of this standard.

Manufacturer shall demonstrate compliance to this section.

11.4.2.3 Pareto analysis of primary root cause of failure mechanisms

Based on the failure analysis of explanted components, the manufacturer shall examine and report by the aggregate summation of all component combinations for each type of receiver–stimulator system, the frequency of failure in relation to root causes or, in the case of the MRE and INC categories, the symptoms or reasons that led to the explantation. For this purpose, the manufacturer shall perform a non-parametric Pareto analysis. The Pareto analysis shall be based on the total, finally investigated components. The results of the analysis shall be reported as a Pareto plot for each receiver–stimulator system to show in rank order the failure mechanisms and observations that contribute to the greatest numbers of explant failures. The number of failure root causes/reasons for explant included in the analysis shall constitute at least 80% of each failure mode category. As applicable, manufacturers should provide any additional analysis to support the aggregated Pareto analysis

Failures or symptoms in the DFE and the MRE meningitis categories for pediatric and adult patients shall be reported separately, as follows:

a) Pediatric patients <10 years old at the time of implantation
b) Patients ≥10 years old at the time of implantation

For the INC and all of the MRE non-meningitis explants, only aggregate reporting (across all patient ages) shall be performed.

Due to privacy laws in certain countries, recipient personal information might not be obtainable. Under such circumstances, the relevant device should be treated and reported as belonging to an adult. Although it is acknowledged that treating patients with unknown age as adults will likely bias the data, the practice is recommended so that the device explantation is recorded and will be included in statistics for all ages. It is also expected that the

occurrence of this practice will be infrequent and that the bias will be small. If the manufacturer determines that there is a high likelihood of bias in the reported data, the report should state this information.

Each failure mechanism/observation reported shall include a clear and concise description of the issue.

Manufacturer shall demonstrate compliance to this section.

Annex F outlines the general procedures for Pareto analysis and shows a template for the Pareto plot for a hypothetical set of DFE devices.

11.4.3 Non-implantable components reliability report to regulatory bodies

11.4.3.1 General requirement

The field performance of sound processors shall be reported in two forms:

a) Monthly return failure rates, in accordance with Section 11.4.3.2
b) Root cause identification of failures using Pareto analysis, in accordance with Section 11.4.3.3

The schedule for publishing the report and the applicable reporting periods are specified in Section 11.4.1.

Manufacturer shall demonstrate compliance to this section.

11.4.3.2 Monthly return failure rates for non-implantable components

The report shall describe the monthly return rates for all models of sound processors that are currently for sale in the United States (Section 11.1.3.2). Data for each model shall be presented separately. Model designations shall comply with Sections 5.1 and 5.2.

The monthly failed component return rate (FCRR) shall be calculated as a percentage using the following formula:

$$\mathbf{FCRR} = \frac{\mathbf{Number\ of\ returned\ failed\ devices\ per\ month} \times \mathbf{100}}{\mathbf{Total\ number\ of\ original\ devices\ sold\ at\ the\ date\ of\ the\ report\ at\ the\ end\ of\ the\ month}}\%$$

Returned failed devices exclude fault-free devices and functioning devices replaced by upgrading to newer models. The total original devices sold exclude units sold as upgrades to replace existing devices in the field. Component return rates shall be presented in both a tabular format and graphically as a stacked column chart, with each column representing one month's market returns as a percentage of the total number of that model sold in the United States. The vertical axis shall show percentages from 0 % to a maximum of 10 %, unless any of the data points exceed 10 %.

The stacked-column chart shall include at least the first four categories of failure: mechanical, electronic, moisture damage, and other/unknown. The tabular presentation shall include categories of mechanical, electronic, moisture damage, other/unknown, and fault-free at a minimum and present the percentages to one decimal place.

The chart shall show monthly return data starting six months after the initial launch of the product, at the latest. The number of months shown in the report shall be the lesser of the number of months that the product has been on the market or the previous two years. Reporting data on a model after it has been removed from sale in the United States is optional; however, the report must state that the product is no longer available for sale.

Examples of tabular and graphical formats for these data are provided in Annex G.

Manufacturer shall demonstrate compliance to this section.

11.4.3.3 Root cause identification of failures using Pareto analysis

Based on the failure analysis of returned non-implantable components, the manufacturer shall examine and report by model the frequency of failure in relation to root causes by performing a non-parametric Pareto analysis. The results

of the analysis shall be reported as a Pareto plot for each model to show in rank order the key failure mechanisms that contribute to the greatest numbers of returns.

Manufacturer shall demonstrate compliance to this section.

Annex F outlines the general procedures for Pareto analysis and shows a template for the Pareto plot.

11.5 Requirements for reporting field reliability data to the public and the clinical community

NOTE—The reliability of a CI system is a key consideration for implant candidates, recipients, and clinicians. This section defines a redacted, standardized method and format for public reporting of the reliability of a CI system based on actual field data.

11.5.1 Schedule and method of reporting to the public and the clinical community

Semiannually, the manufacturer shall publish reliability reports publicly for the implantable and external devices specified in Section 11.5.2. The reports shall be provided at the end of the first and third quarters of the calendar year and shall report data collected through the end of the fourth quarter of the previous year or the second quarter of the current year, respectively.

Manufacturer shall demonstrate compliance to this section.

11.5.2 Reliability data for public reporting

The inclusion criteria for the reporting of reliability data for implantable and non-implantable components are described in Section 11.1.3. Global field data shall be reported for the aggregate summation of all component combinations for each type of receiver–stimulator system. These component combinations shall be named according to the commercial product designation of the dominant receiver–stimulator system.

The term “explant” shall be referred to as “removal” in materials released to the public (e.g., Medical Related Removal, Device Failure Removal).

The reliability reports for public distribution shall include four items:

a) For each type of receiver–stimulator system, the cumulative failure percentage (CFP) shall be reported graphically as a function of the number of years since implantation (in accordance with Section 11.4.2, except that the analysis interval shall be 12 months). Per Section 11.4.2.2, data shall be reported for adult and pediatric patients separately and combined. A common graphical format to be used by all manufacturers is provided in Annex H.

b) For each model of implantable component, a tabular listing of failure rates for the following subcategories shall be provided:
   i. Medical Related Explants (MRE)
   ii. Device Failure Explants (DFE)
   iii. Inconclusive Failure Analysis (INC)

   In accordance with Section 11.4.2.2, data shall be reported for adult and pediatric patients, separately and combined.

   A common table format to be used by all manufacturers is provided in Annex H.

   NOTE—Minimum classifications for failure analysis of implantable components for public reporting are shown schematically in Figure 11.

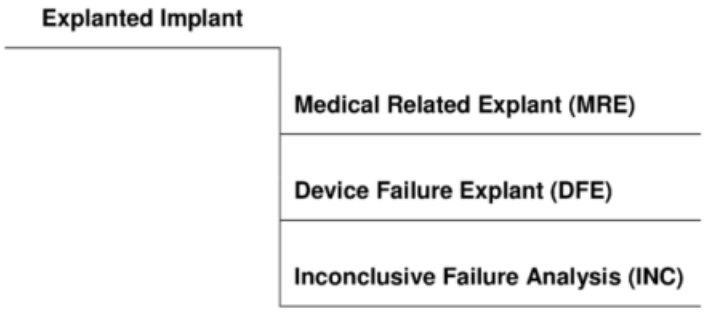
c) For each sound processor type, monthly return failure rates shall be provided per Section 11.4.3.2. A common graphical format to be used by all manufacturers is provided in Annex G.

   NOTE—Minimum classifications for failure analysis of sound processors for public reporting are shown schematically in Figure 12.

d) Supporting text shall describe how to interpret the reliability data including the graphical analysis. This text shall also include definitions of all terms used in the report. An example of the text that could be used is provided in Annex H (the section on "How to Read a Manufacturer's Reliability Report").

Materials reported to the public shall be posted on the manufacturer's website with prominent links from the home page.

Manufacturer shall demonstrate compliance to this section.



NOTE 1—The term Explanted Implant shall be referred to as Removed Implant in the materials released to the public.

NOTE 2—Devices that are out-of-service, but not explanted, are not included in the above reporting plan.

Figure 11—Minimum classifications for failure analysis of implantable components for public reporting

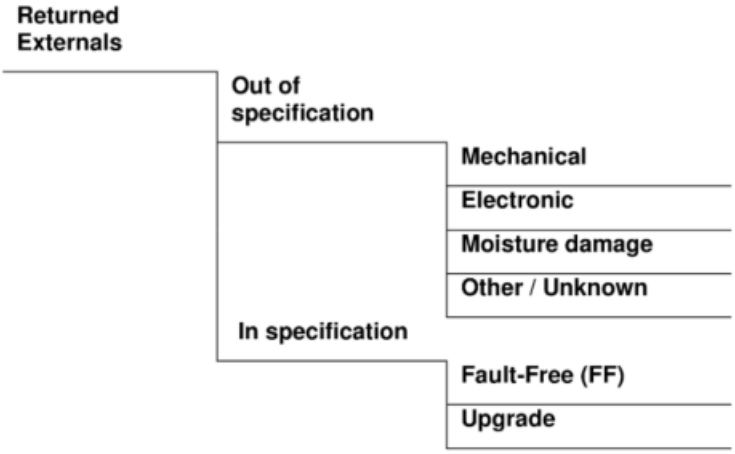


Figure 12—Minimum classifications for failure analysis of sound processors for public reporting

12 Information on use, warnings, and hazards

The accompanying documentation shall be written at no greater than an eighth-grade level.

NOTE—In general, the information provided in accordance with the requirements in this section is non-proprietary and is not subject to the proprietary limits stated in the scope statement in Section 0.

12.1 Specification of product data sheets

The accompanying documentation shall include information regarding the general specifications of the medical device in the summary form of product data sheets. At minimum, data sheets should be included for the implantable device, the electrode array, the sound processing strategies, the sound processor hardware, and, if applicable, the remote controls.

The information included in the product data sheets shall be for public distribution and should not include proprietary information. The distribution of the product data sheets to the public and clinical community shall be available on the company website.

See Annex I for example templates of product data sheets.

Manufacturer shall demonstrate compliance to this section.

12.2 Instructions on proper use of the device by the physician, audiologist, and/or patient

The accompanying documentation shall include instructions for using the cochlear implant system , so that physicians, audiologists, and, when appropriate, the patient are able to use the device correctly.

Manufacturer shall demonstrate compliance to this section.

12.2.1 Manufacturer contact information

The accompanying documentation shall include the name, postal address, and telephone number of the manufacturer or, if the manufacturer does not have a registered place of business in the community, the name, postal address, telephone number, and address of the manufacturer's authorized representative.

Manufacturer shall demonstrate compliance to this section.

12.3 Information regarding device and accessory selection

The accompanying documentation shall provide information allowing the physician and/or audiologist to select a suitable device, its accessories, and related features (e.g., processing strategies, noise reduction modes, auxiliary inputs/devices).

Manufacturer shall demonstrate compliance to this section.

12.4 Information on potential hazards at implantation

The accompanying documentation shall include information on avoidable hazards at implantation.

Manufacturer shall demonstrate compliance to this section.

12.5 Warnings regarding maintaining proper operating environment

The accompanying documentation shall contain warning notices appropriate to the intended use and normal function of the cochlear implant system. Also, information should be included about the hazards caused by interference either from or to the implantable device during other clinical procedures or medical treatments. Examples of such treatments are those described in (but not limited to) Sections 21.1, 22.1.1, 22.1.2, 22.1.3, and 22.1.4. If restrictions apply during treatments (e.g., proximity, energy power levels), the manufacturer shall also declare in the labeling

and/or the instructions those circumstances and the limits beyond which hazards might potentially exist for the patient. Specific labeling requirements for MRI safety and immunity are described in Section 12.25.

Manufacturer shall demonstrate compliance to this section.

NOTE—Although the tests have been designed to demonstrate the continued safe performance of the implant system during or following certain clinical procedures or medical treatments, warnings might still be necessary if the performance of the implant system remains unaffected but hazards might exist for the patient because of the presence of the implant system during other clinical procedures or medical treatments.

12.6 Warning of potential damage because of electrical currents from medical treatments

The accompanying documentation shall warn that if the patient with the cochlear implant system is subsequently given any medical treatment in which an electrical current is passed through his or her body from an external source, either the device should first be deactivated or care should be taken to monitor the functioning of the cochlear implant system during the initial stages of treatment. Examples of such treatments are those referred to in (but not limited to) Sections 22.1.3 and 22.1.4.

Manufacturer shall demonstrate compliance to this section.

12.7 Warning to avoid ultrasonic exposure of implanted device

The accompanying documentation shall warn that implanted parts of a cochlear implant system should not be exposed to therapeutic levels of ultrasound energy, because the device could inadvertently concentrate the ultrasound field and cause harm. See Section 22.1.1.

Manufacturer shall demonstrate compliance to this section.

12.8 Warning of potential damage by therapeutic ionizing radiation

The accompanying documentation shall warn, if applicable, that electronic components in a cochlear implant system can be damaged by therapeutic ionizing radiation and that any damage to the device might not be immediately detectable.

Manufacturer shall demonstrate compliance to this section.

NOTE—Cochlear implant systems can withstand specific levels of therapeutic ionizing radiation. According to Section 12.5, the manufacturer is required to provide information on the maximum allowable dosage, as determined in accordance with the test described in Section 22.2.2.

12.9 Warning that the implantable device is not for reuse

The accompanying documentation shall include a warning that implantable parts of the CI system are not to be reused if they have previously been implanted in another patient.

Manufacturer shall demonstrate compliance to this section.

12.10 Information on exceptional environments and constraints on handling the implant

The accompanying documentation shall include information about any exceptional environmental or handling constraints (e.g., protection from impact, vibration, temperature, pressure, humidity, or electrostatic discharge) that are necessary to allow the active implantable medical device to be correctly handled and stored. See Sections 16.1, 16.2, 23.1.1, 23.1.2, 23.1.3, 24.2.1, and 25.1.

Manufacturer shall demonstrate compliance to this section.

12.11 Warning of precautions for adverse environments

This section applies to both implantable and non-implantable components of the device system.

12.11.1 Warning of environments adverse to the patient

The accompanying documentation for patients and clinicians shall warn of precautions to be taken to prevent adverse effects on the patient because of specific adverse environmental conditions (e.g., electromagnetic interference, extreme temperature, variations of pressure).

The accompanying documentation for non-implantable parts shall include warnings in accordance with IEC 60601-1 and IEC 60601-1-2.

Manufacturer shall demonstrate compliance to this section.

12.11.2 Warning of environments adverse to the device

The accompanying documentation for patients and clinicians shall warn of precautions to be taken to prevent adverse effects on the device because of specific adverse environmental conditions (e.g., electromagnetic interference, extreme temperature, variations of pressure).

The accompanying documentation for non-implantable parts shall include warnings in accordance with IEC 60601-1 and IEC 60601-1-2.

Manufacturer shall demonstrate compliance to this section.

12.12 Warning to the patient to seek medical advice before entering adverse environment

The accompanying documentation shall include a warning that the patient should be advised to seek medical guidance before entering environments that could adversely affect the operation of the cochlear implant system . Such environments include areas protected by a warning notice prohibiting entry by patients fitted with a pacemaker or other active implantable medical device.

Manufacturer shall demonstrate compliance to this section.

NOTE—Some environments that might present hazards to patients with various types of electronic implants are commonly indicated by warning notices addressed only to “pacemaker patients.” Such warnings might be relevant to other active implantable medical devices, although, without specific advice, a patient might decide to ignore the warning if not fitted with a pacemaker. This subsection is not intended to encourage patients to disregard warning notices, but rather to ensure that patients with an active implantable medical device other than a pacemaker recognize that a warning addressed to pacemaker patients might be important to them.

12.13 Warning of precautions to prevent adverse effects that could be caused by performance changes

The accompanying documentation shall warn of recommended precautions that should be taken to prevent adverse effects caused by performance changes in the cochlear implant system (See Section 20).

Manufacturer shall demonstrate compliance to this section.

12.14 Information about administration of medicinal products

If applicable, the accompanying documentation shall include information regarding the medicinal products that the cochlear implant system is designed to administer. (See also Section 20.4.)

NOTE—This subsection does not apply to any medicinal substance that forms an integral part of the cochlear implant system .

Manufacturer shall demonstrate compliance to this section.

12.15 Warning regarding tissue damage that could be caused by excessive coil retention forces and the need for clinical monitoring and management

External devices that apply pressure to the skin for retention purposes can restrict the blood circulation in the skin, leading to skin irritation or, in severe cases, blistering and necrosis of the skin. If the external device's retention mechanism results in an applied pressure to the skin that can exceed 3.7 KiloPascals (kPa) in normal use, a warning shall be provided in the instructions for use. The upper pressure limit of 3.7 kPa is based on the recommendation of Raicevich, Burwood, and Dillon (2008). The warning shall include advice to the patient or caregiver to be aware of the signs of skin irritation, as well as advice to the physician to ensure that the clinical care includes monitoring and management of possible skin irritation. The warning shall also state that in the case of significant skin irritation, blistering, or signs of skin breakdown, use of the device should be suspended until the wound site can be assessed by the clinical cochlear implant caregivers. See Section 16.2.

Manufacturer shall demonstrate compliance to this section.

12.16 Warning regarding the magnetic field from headpiece coil causing the reprogramming of magnetic shunts

Clinical reports have shown that magnetic fields created by cochlear implant headpiece coil retention magnets are sufficient in strength to alter valve programming when brought into the vicinity of magnetic shunts. A warning shall be provided advising the patient or caregiver to be aware of the possibility and signs of such reprogramming. In cases in which the patient is considered at risk for such reprogramming, alternative means of headpiece coil placement and/or retention shall be provided. See Section 16.1.

Manufacturer shall demonstrate compliance to this section.

12.17 Warning of possible side effects during normal use

The accompanying documentation shall warn of possible side effects during normal use (e.g., overstimulation), including potential risks from electronic interference. See Section 20.4.

Manufacturer shall demonstrate compliance to this section.

12.18 Warning of possible choking hazards associated with use of long cables with infants and young children

The accompanying documentation shall warn of possible choking hazards associated with using long cables with infants and young children. See Section 26.3.7.

Manufacturer shall demonstrate compliance to this section.

12.19 Warning of hazards associated with swallowing small parts

The accompanying documentation shall warn of possible ingestion hazards associated with swallowing small parts, especially magnets and batteries. Recommendations regarding the actions to take in the event of ingestion shall be provided.

Manufacturer shall demonstrate compliance to this section.

12.20 Information regarding access to reliability information for clinicians and public

The labeling shall include information about the public availability of reliability reports (see Section 11.5). Posted information shall be dated according to publication and expiration dates and include instructions on how current reliability information can be obtained.

Manufacturer shall demonstrate compliance to this section.

12.21 Information regarding the availability of field assessment information for clinicians

The labeling shall include information for clinicians about the availability of diagnostic tools, guidelines, and technical support for assessing device function in the field. See Section 11.1.6.

Manufacturer shall demonstrate compliance to this section.

12.22 Labeling of ingress protection

If the labeling includes a claim for ingress protection (IP), as defined in Section 26 and IEC 60529, the labeling shall include a description of each IP rating (i.e., particulate, moisture) in language that can be easily understood by the patient. This labeling shall include the product data sheets (see Section 12.1). The usage and test method must also be included so that patients understand the time of exposure, the depth of water exposure, the type of water, and the amount of cycles to which the product can be exposed.

Manufacturer shall demonstrate compliance to this section.

12.23 Informational summary of safety and effectiveness data

The labeling shall include a summary of the safety and effectiveness data (e.g., clinical study data). Labeling may be updated at the request of the regulatory body.

Manufacturer shall demonstrate compliance to this section.

12.24 Information about immunization of cochlear implant candidates

Labeling shall provide information about recommendations for immunization of patients prior to implantation. See Section 15.3.

Manufacturer shall demonstrate compliance to this section.

12.25 Information about MRI safety and immunity claims

12.25.1 Definitions

This section applies to the accompanying documentation as defined below. The terms below are used for the purpose of this document and may be referred to by other names by a given manufacturer.

a) *Patient Card:* Card issued to the patient by the manufacturer that identifies the implanted system
b) *Patient Information:* Instructional/informative document issued to the patient by the manufacturer
c) *Implant Information:* Instructions for use issued by the manufacturer for implantation of the device
d) *MR Procedure Manual:* Instructions for MR scanning issued by the manufacturer

12.25.2 Applicability of labeling requirements

Table 8 designates by subsection the MRI labeling requirements in Section 12.25.3 that apply to each accompanying document. All devices are not accompanied by all of these pieces of documentation. Some of this information may be combined into a single document.

Manufacturer shall demonstrate compliance to this section.

Table 8—Applicability of MRI labeling requirements

Document Type	Audience for Labeling	Applicable MRI Labeling Requirements (Listed by subsection of Section 12.25.3)
Patient Card	Patient, radiologist/MR technologist	a, d, e, f (optionally)
Patient Information	Patient	a, b, c
Implant Information	Implanting physician	a, b, d, f
MR Procedure Manual	Referring physician (prescribes MR scan), radiologist/MR technologist	a, b, c, d, f, g, h, i, j

12.25.3 MRI labeling requirements

The individual requirements below are applicable only as specified in Table 8. See also Section 21.1

a) The term "MR Conditional" or "MR Unsafe," together with the corresponding icon, shall be used as specified in ASTM F2503-13.
b) The accompanying documentation shall contain general warnings regarding the hazards that could be caused by performing an MR procedure on a patient with a cochlear implant
c) The accompanying documentation shall direct the patient to consult with the treating physician prior to an MR scan and shall contain a web address and phone number at which the patient can obtain additional information.
d) The accompanying documentation shall contain a statement directing users to the current MR Conditional labeling (e.g., URL and phone number).

   NOTE—An example statement is "This person is implanted with a *** *dev*ice and may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction. Full MRI safety information is available in the MRI section of the physician manual, which can be obtained at www.***** or by calling *****."

e) Where possible, the accompanying documentation shall unambiguously identify the device and all of the system components.
f) The conditions under which a patient with an implant can be scanned safely shall be provided. This information shall also include the patient risks associated with not following the instructions for safe scanning provided by the manufacturer (e.g., risks due to implant location, abandoned or fractured leads, and other implants).
g) The accompanying documentation shall include instructions for safely performing the MR procedure on the patient. This might include patient preparation, procedural instructions, special implant operating modes, peripheral equipment needed, necessary patient monitoring or intervention during and after scanning, or other similar instructions to ensure safety.
h) The accompanying documentation shall describe all intended and expected device operation during an MR scan.
i) The device could interfere with the acquisition of MR data, resulting in artifacts that could compromise MR images. The accompanying documentation shall contain a statement concerning device-induced MR image artifacts.
j) The accompanying documentation shall include information about possible implant magnet weakening, including the expected percentages of weakening after 1 exposure and after 10 exposures. See Section 21.7.

   NOTE—ASTM F2119 specifies a test method for evaluating MR image distortion artifacts from passive implants and may be used to evaluate the MR image distortion artifacts from an active implantable medical device.

The MR Procedure Manual shall contain a separate section for the physician.

Manufacturer shall demonstrate compliance to this section.

12.25.4 Availability of Labeling

The most recent revision of the MR Procedure Manual shall be made available by one or more of the following means:

a) The manufacturer's website
b) The manufacturer's phone number (e.g., Tech Services)

NOTE—It is recommended that labeling be made available on the manufacturer's website.

13 General arrangement of the packaging system

13.1 Implant in a non-reusable sterile barrier system

Implantable parts of active implantable medical devices shall be supplied in a non-reusable sterile barrier system. (See Section 13.3.) The non-reusable pack shall be designed to be sealed, yet allow its contents to be sterilized by the manufacturer.

Manufacturer shall demonstrate compliance to this section.

NOTE—The non-reusable pack becomes the sterile barrier system when the pack and its contents have been sterilized. The requirement for sterility is addressed in Section 15.1.

13.2 Non-reusable sterile barrier system in protective packaging

The non-reusable sterile barrier system shall be enclosed in the protective packaging.

Manufacturer shall demonstrate compliance to this section.

NOTE—The protective packaging protects the non-reusable sterile barrier system and its contents against the rigors of transport and storage and ensures that the accompanying documentation is available at the point of use. (See also Section 13.3.)

13.3 Construction and validation of the packaging system

Implantable components shall be contained within a packaging system designed and manufactured to ensure continued sterility of the contents until the packaging system is damaged or opened by the user. The packaging system shall consist of a sterile barrier system and protective packaging. The sterile barrier system is the minimum package that maintains sterility of the device until the point of use. The protective packaging prevents damage to the sterile barrier system and its contents during transport and storage until the time of use. The general requirements for the construction and validation of the packaging system are contained in ANSI/AAMI/ISO 11607, Parts 1 and 2. Additional guidelines for application of ANSI/AAMI/ISO 11607-1 and ANSI/AAMI/ISO 11607-2 in the U.S. regulatory environment are described in AAMI Technical Information Report 16775:2014.

Manufacturer shall demonstrate compliance to this section.

NOTE—ANSI/AAMI/ISO 11607-1 is the generic standard that specifies requirements for single-use materials and reusable containers for packaging terminally sterilized medical devices. ANSI/AAMI/ISO 11607-2 specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of sterile barrier systems and packaging systems.

14 Markings on the packaging system and the cochlear implant device

NOTE—In general, the information provided in the marking of a cochlear implant device is to be useful for the clinician in applying the device in a course of medical treatment. Adding information that is irrelevant to this purpose might obscure information that is essential to the proper use of the device.

14.1 General requirements

14.1.1 Prominent display of warning notices

Any warning notices required by this standard shall be prominently displayed. To prevent undue risk to patients, required warnings should be immediately apparent, neither too small nor obscured by other warning notices.

Manufacturer shall demonstrate compliance to this section.

14.1.2 Device traceability

The implanted parts of devices and components of those parts shall be identified in such a way as to allow any necessary action to be taken following the discovery of a possible hazard pertaining to any implanted part.

Compliance will be verified by review of the manufacturer's explanation of the relationship between the identity of the cochlear implant system and the identities of its component parts.

Manufacturer shall demonstrate compliance to this section.

14.2 Markings on the protective packaging

NOTE—In general, markings on the sales packaging should be minimized to avoid non-essential information, which reduces the clarity of the essential data required by this part of this standard.

14.2.1 Markings for radioactivity

If the protective packaging contains any radioactive substance, it shall have markings that state the type and activity of the radioactive substance.

Manufacturer shall demonstrate compliance to this section.

NOTE—Packages containing radioactive sources might be subject to additional specific regulatory controls.

14.2.2 Identification of manufacturer

The protective packaging shall bear the manufacturer's name and contact information.

Manufacturer shall demonstrate compliance to this section.

14.2.3 Month, day, and year of manufacture

The protective packaging of implantable parts of a cochlear implant system shall bear the month, day, and year of manufacture, expressed in numerals, as specified by ISO 8601.

Manufacturer shall demonstrate compliance to this section.

14.2.4 Use-before date

The protective packaging of implantable parts of a cochlear implant system shall bear the "use before" date, as required per ANSI/AAMI/ISO 11607-1.

Manufacturer shall demonstrate compliance to this section.

14.2.5 Description of device

If a cochlear implant system is supplied in separate subassembly packaging, each individual protective package shall bear a description of the contents of the packaging, the model designation or part number, and, if applicable, the batch number or the serial number, whichever provides more specificity in identifying the component.

Manufacturer shall demonstrate compliance to this section.

14.2.6 Intended use of device

The protective packaging of implantable parts of a cochlear implant system shall carry a clear description of the intended use of the device, if this is not obvious from the device description required in Sections 14.3.7 and 14.3.8.

Manufacturer shall demonstrate compliance to this section.

14.2.7 Additional identifying description of implantable device

The protective packaging of implantable parts of a cochlear implant system shall bear any additional information and relevant characteristics, as necessary, to identify the device.

Manufacturer shall demonstrate compliance to this section.

14.2.8 Statement of sterilization (protective packaging)

The protective packaging of implantable parts of a cochlear implant system shall bear a statement that the contents of the package have been sterilized.

Manufacturer shall demonstrate compliance to this section.

14.2.9 Declaration of sterilization (accompanying documentation)

The accompanying documentation shall include a declaration that the implantable parts of the cochlear implant system have been sterilized.

Manufacturer shall demonstrate compliance to this section. (See also Section 14.3.3.)

14.2.10 Guidelines on device sterilization methods

If applicable, the accompanying documentation shall include instructions on the sterilization method of reusable tools/accessories that are delivered non-sterile. The documentation shall also include cleaning instructions for reprocessing, if applicable. This does not apply to single use devices.

The accompanying documentation shall include instructions on the actions to be taken in the event that the sterile barrier system has been damaged or has been previously opened.

Manufacturer shall demonstrate compliance to this section.

14.2.11 Identification of accessories

The markings on the protective packaging of implantable parts of a cochlear implant system shall identify the accessories within the packaging or, if there is insufficient space on the protective packaging, the contents shall be identified within the protective packaging.

Manufacturer shall demonstrate compliance to this section.

14.2.12 Identification of required connectors or configurations

If the intended use of an implantable part of a cochlear implant system enclosed within the protective packaging requires that it be connected to another device or accessory not included in the package, the protective packaging shall identify the connector types or configurations required.

Manufacturer shall demonstrate compliance to this section.

14.2.13 Exceptional environmental or handling constraints

The protective packaging shall bear information about any exceptional environmental or handling constraints (e.g., protection from impact, vibration, temperature, pressure, or humidity) necessary to allow the devices to be correctly handled and stored (See Section 13.3).

Manufacturer shall demonstrate compliance to this section.

NOTE—See Sections 13.3, 23.2.1, 23.2.2, 23.2.4, 24, and 25 for requirements related to exceptional transport and storage conditions.

14.2.14 Designation of special-use devices

If the device is intended for a special purpose, the protective package shall bear a description of the special purpose (e.g., “custom-made device” or “exclusively for clinical investigations”).

Manufacturer shall demonstrate compliance to this section.

14.2.15 Use of symbols on sales packaging and the sterile barrier system

Symbols used on sales packaging and the sterile pack shall comply with ISO 15223-1:2012 to the extent that this standard is recognized by the FDA. The FDA recognizes the entire standard except for the following:

a) The FDA recognizes selected symbols in this standard only for use on the label and in the labeling of medical devices intended for professional use. The FDA does not recognize these or any symbols for use in the labels and labeling of over-the-counter or prescription home-use devices unless accompanied by equivalent text in English.
b) The FDA excludes from recognition ISO 15223-1 symbols 5.2.6 through 5.2.9, 5.3.1 through 5.3.4, 5.3.8, 5.3.9, 5.4.5, 5.6.1 through 5.6.6, and 5.7.1.

The labeling applies to the sales packaging and sterile pack containing the device that has the symbols, but not to the shipping box.

Manufacturer shall demonstrate compliance to this section.

14.3 Markings on the sterile barrier system

NOTE—In general, markings on the sterile barrier system should be minimized to avoid non-essential information, which reduces the clarity of the essential data required by this standard.

14.3.1 Multiple products in similar sterile barrier systems

If a manufacturer has multiple products packaged in similar sterile barrier systems and with similar markings, the markings describing the unique contents of the sterile barrier system shall be clearly distinguishable and easily identifiable by the users handling the sterile barrier system.

Manufacturer shall demonstrate compliance to this section.

14.3.2 Identification of the manufacturer and address of the manufacturing location

The sterile barrier system shall bear the name or trade name of the manufacturer and the address (city and country) of the manufacturing location.

Manufacturer shall demonstrate compliance to this section.

14.3.3 Statement of sterilization and identification of sterilization method

The sterile barrier system shall bear a statement that the system and its contents have been sterilized and indicate the method of sterilization used (see Section 14.3.4 and ISO 15223-1:2016 for recommended symbols). Certain

symbols from ISO 15223-1:2016 are excluded from use on the sterile barrier system by the FDA (see Section 14.2.15).

Manufacturer shall demonstrate compliance to this section.

14.3.4 STERILE symbol

In accordance with ISO 15223-1, the following symbol shall be displayed prominently on the sterile barrier system:



Manufacturer shall demonstrate compliance to this section.

14.3.5 Month, day and year of manufacture

The sterile barrier system shall bear the month, day, and year when the packaged device was manufactured, expressed according to the requirements of Section 14.2.3.

Manufacturer shall demonstrate compliance to this section.

14.3.6 Use-before date

The sterile barrier system shall bear the “use before” date, expressed according to the requirements of Section 14.2.4.

Manufacturer shall demonstrate compliance to this section.

14.3.7 Description of device

The sterile barrier system shall bear a description of the device, as required by Section 14.2.5.

Manufacturer shall demonstrate compliance to this section.

14.3.8 Identification of contents

The markings on the sterile barrier system shall identify the contents, unless the sterile barrier system is transparent and the contents are visible.

Manufacturer shall demonstrate compliance to this section.

14.3.9 Identification of required connectors or configurations, if applicable

If the intended use of a device enclosed in a sterile barrier system requires that it be connected to other devices or accessories not included within the system, the sterile barrier system shall identify the connector types or configurations needed, as required by Section 14.2.12.

Manufacturer shall demonstrate compliance to this section.

14.3.10 Instructions for opening the sterile barrier system

The sterile barrier system shall bear instructions for opening the system.

Manufacturer shall demonstrate compliance to this section.

14.3.11 Designation of special-use devices

If the device is intended for a special purpose, the sterile barrier system shall bear an indication of the special purpose (e.g., “custom-made device” or “exclusively for clinical investigations”).

Manufacturer shall demonstrate compliance to this section.

14.4 Markings on the cochlear implant system

14.4.1 Individual device identification

As far as practicable and appropriate, the cochlear implant system shall bear the name or trademark of the manufacturer, the model designation of the device, and, if applicable, the batch number or serial number of the device. These markings shall be indelible.

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

The test procedure is as follows:

1) Rub the markings by hand, without undue pressure, for 15 (+5, -0) seconds with a cloth rag soaked in methylated spirit at ambient temperature.
2) Rub the markings for 15 (+5, -0) seconds with a cloth rag soaked in water at ambient temperature.
3) Inspect the markings and verify that they remain clearly legible.

Manufacturer shall demonstrate compliance to this section.

14.4.2 Unequivocal identification

Implantable parts of a cochlear implant system shall be unequivocally identifiable (particularly with regard to the model of device), when necessary, without the need for a surgical intervention. The manufacturer shall determine the methodology and document the method in the labeling.

Compliance will be verified by inspection of the procedure defined by the manufacturer in the instructions for use (see Section 14.4.3).

NOTE—This section addresses the need for any device in use to be identified without the clinician performing a surgical operation. In practice, it might not be possible to add additional markings to implant systems. The present state of the art is to identify the model and/or manufacturer through an x-ray outline profile, enabling a suitable telemetry device to be selected. Visual indicators

Any visual indicators carried on a cochlear implant system shall be understandable with reference to the accompanying documentation, taking into account the training and knowledge of the likely user. Any symbols or identification colors used shall conform to international standards. Certain symbols specified in ISO 15223-1 are excluded from use by the FDA (see Section 14.2.15). If no applicable standards exist, the symbols and colors shall be described in the documentation supplied with the device.

Manufacturer shall demonstrate compliance to this section.

14.4.3 Interpretation of unequivocal identification markings

The accompanying documentation shall include an explanation of how to interpret the identification code required by Section 14.4.2.

Manufacturer shall demonstrate compliance to this section.

15 Safety from unintentional biological effects of the cochlear implant system

15.1 Sterility of implantable device and tools

Any implantable part of a cochlear implant system or other parts enclosed in the non-reusable sterile barrier system (see Section 13.3) and not contained within an implantable, hermetically sealed, impermeable container shall be sterile.

Compliance will be verified if the process validation records provided by the manufacturer establish that the non-reusable sterile barrier system has been sterilized by a validated process (e.g., according to ISO 14937) that demonstrates that the product has achieved the required sterility assurance level (SAL) of 10^{-6}.

Manufacturer shall demonstrate compliance to this section.

NOTE—To avoid further handling and processing in the hospital, implantable parts of active implantable medical devices are to be supplied sterile in a non-reusable sterile barrier system. If for convenience other parts are included in the non-reusable sterile barrier system, they, too, must be sterile to avoid contamination of the implantable parts. Material that is contained within a hermetically sealed container throughout the lifetime of the device is not required to be sterile.

15.2 Particulate matter

Any implantable part of the cochlear implant system that is intended in normal use to be in contact with body fluids shall cause no unacceptable release of particulate matter when the device is used as intended by the manufacturer.

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

The test method shall be performed in accordance with ISO 14708-7:2013, Clause 14.2.

Manufacturer shall demonstrate compliance to this section.

15.3 Immunization protection against increased risk of infections due to surgery and device placement

Children and adults are at increased risk of acute otitis media and meningitis due to surgery and chronic device placement as part of cochlear implantation. Clinical practice recommendations (Rubin, Papsin et al., 2010) and regulatory bodies (CDC [1] and FDA) advise that implant candidates should have appropriate vaccinates to protect against infection arising from surgery and device placement.

Labeling shall include the reference to the CDC website for currently available recommendations[1] regarding the use of vaccinates in cochlear implantation (see Section 12.24).

Manufacturer shall demonstrate compliance to this section.

16 Safety of secondary features of the cochlear implant system

16.1 Prevention of magnetic field interference with other medical devices

Manufacturers should address the potential consequences of magnetic field interference with other medical devices (e.g., programmable ventriculoperitoneal shunts) and, where possible, provide methodologies and clinical guidance to minimize such effects. (See Section 12.16.)

---

[1] CDC Vaccines and Immunizations Factsheet. *Use of Vaccines to Prevent Meningitis in Persons with Cochlear Implants.* Available at: http://www.cdc.gov/vaccines/vpd-vac/mening/cochlear/dis-cochlear-gen.htm

Manufacturer shall demonstrate compliance to this section.

NOTE—This section was developed in response to the documented interference between coil/headpiece magnetics and programmable shunts (Wiet and El-Kashlan, 2009; An et al., 2011).

16.2 Prevention of harm caused by headpiece retention

NOTE—This section is only applicable to systems that use magnetic attraction to attach an external device (such as a transmitter coil or headpiece) to the head of a recipient.

The manufacturer shall ensure through labeling and/or device design that the pressure applied by an external part to the recipient's skin complies with the specification for the device.

During clinical application, the maximum pressure applied by the coil should not exceed 3.7 kPa, unless there is a warning in the labeling (see Section 12.15). For some patients, a lower pressure level might be required to maintain proper vascular flow in the underlying skin. The appropriate pressure level is determined by the physician. In cases in which the pressure level necessary to maintain vascular flow is insufficient to maintain coil retention, the manufacturer should provide alternative means of coil retention or the coil surface area should be suitably increased to reduce the pressure.

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

Compliance will be verified by inspection of the test procedures and results provided by the manufacturer.

Manufacturer shall demonstrate compliance to this section.

NOTE 1—For coil designs allowing adjustment of magnet position, the design should ensure that no part of the adjustment mechanism can extend beyond the contact plane of the coil so that focal pressure points can be avoided.

NOTE 2—For designs allowing stacking of magnets, provision should be made to minimize the possibility of exceeding the recommended maximum coil pressure.

Because excessive pressure applied to the skin by a device can lead to skin irritation, it is important that pressure on the skin is a controlled parameter in the cochlear implant system design (see Section 12.15). The upper pressure limit of 3.7 kPa is based on the recommendations of Raicevich, Burwood, and Dillon (2008).

17 Safety of electrical stimulation

17.1 Electrical safety of applied signals to non-implantable parts

Electrical audio inputs into non-implantable parts of an implant system shall comply with the requirements for electrical safety of the hearing aid standard, IEC 60601-2-66. Other electrical inputs or outputs of non-implantable parts of an implant system that allow the non-implantable part to be connected to supply mains or mains powered devices that do not meet the requirements for protection against electrical hazards specified in IEC 60601-1 shall either contain or be provided with an external protective interface that complies with the applicable sections in IEC 60601-1 regarding protection against electrical hazards. Small external devices such as behind-the-ear sound processors cannot fully meet the requirements for leakage currents of IEC 60601-1 because of the voltage applied to the patient from the batteries. See Section 7.2.

A protective interface is not required for battery-powered devices when used stand-alone.

Compliance will be verified by inspection of the medical electronic equipment and the risk analysis provided by the manufacturer.

Manufacturer shall demonstrate compliance to this section.

17.2 Direct current leakage limit under use conditions

Except for their intended function, implantable parts of an implant system shall be electrically neutral when in contact with the body. Sustained small direct currents, or leakage, from implanted electrodes could cause tissue damage or electrode corrosion. Leakage current of no more than 0.1 μA shall be sustained in any of the current pathways when the device is in use. The safe limit has been established at 0.1 μA in accordance with opinion in current literature (Shepherd et al., 1999).

The DC leakage measurement shall be carried out on a device operating under conditions representative of real stimulation using defined, repeatable stimulation sequences while the electrodes and implant are immersed in a 0.90 % w/v saline solution. The device settings, including a rationale for their choice and the measurement methodology, shall be documented with the test results The test procedure shall include steps to ensure that the implant is functionally stimulating and that the electrode surfaces are free from bubbles that could impede current flow. The impedance of all electrodes shall be determined to be in the normal range (section 8.2) before measurements are taken to confirm the absence of shorts, opens, air bubbles, and other problems that could interfere with the results.

An appropriate test and measurement system shall be used to reliably measure the leakage current for each electrode. If required, steps shall be taken to ensure that noise from any transcutaneous link does not interfere with the measurement. A filter circuit equivalent to a single-pole, passive, low-pass filter with a time constant of ≥ 1 second or a cutoff frequency of ≤ 0.16 Hz may be used to attenuate the time-varying component of the waveform so that the leakage current can be measured. The test system shall be calibrated to minimize measurement errors caused by component and instrument tolerances; the calibration results shall be included in the test results.

The implant being tested shall be modified to allow the insertion of the above measurement circuit serially into each of its electrode leads. Any extra-cochlear electrodes associated with the implant (including the implant case) shall also be connected to the above measurement circuit. If required for this test, electrodes equivalent to the system's extra-cochlear electrodes shall be placed in the saline solution and shall have the same exposed area and be of the same material as the original extra-cochlear electrodes.

The test measurements shall be obtained under at least the following conditions:

a) A control condition with the device powered down
b) A condition with the device powered but providing no stimulation
c) A condition with the device powered and providing sustained stimulation corresponding to the simultaneous use of both maximum charge density and maximum current level

NOTE—Some systems might not permit the simultaneous use of maximum charge density and maximum current level because of the quantization of available pulse widths. In this case, the maximum charge density shall be used, and the pulse width shall be chosen to maximize the current level.

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

Compliance will be verified by inspection of the design verification test procedures and the test results provided by the manufacturer.

Manufacturer shall demonstrate compliance to this section.

17.3 Charge and charge density limits for biphasic, charge-balanced pulses

The magnitude of the charge, Q, delivered per phase through any electrode of a cochlear implant system shall not exceed the lesser of the following:

a) A ***Charge and Charge Density Limit*** equal to the square root of the product of 10^k $\mu C^2/cm^2$ and the electrode area, A, in cm^2 and expressed formulaically as:

$$\mathbf{Q \leq \sqrt{A10^k}} \quad \textbf{and} \quad \mathbf{k = 1.75} \qquad \textbf{(8)}$$

where:

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Q is the charge delivered per phase to the electrode in microcoulombs (μC) and is defined as the modulus of the integral of the specified current over the phase duration, starting at zero when the implant system is at rest

A is the geometric area of the electrode in cm^2

10^k is a constant describing the charge and charge density boundary limit (Shannon, 1992)

k is a dimensionless multiplier used to set the boundary (Shannon, 1992)

This limit protects against neuronal damage observed in stimulation of brain cortical tissue (McCreery et al., 1990). Shannon (1992) developed a formula, based on a combination of charge and charge density, that predicts the point at which damage occurs. Shannon expressed the formula for this limit in terms of a k value that, if exceeded, places stimulation in a region where damage can occur. There is no consensus on the exact mechanism of nervous tissue damage during electrical stimulation. Besides neural hyperactivity (Agnew et al., 1990, 1993; Olney et al., 1983), there are other factors such as generation of platinum compounds, some of which might be toxic (Agnew et al., 1977; Robblee et al., 1983; Kumsa et al., 2016), or non-metallic harmful chemical species (Merrill et al., 2005; Mortimer et al., 1980; Morton et al., 1994).

Manufacturers of neural stimulators typically have used a value of k = 1.5 for establishing a safe limit. The reason that k = 1.75 has been specified in this standard is that the k = 1.5 safety limit was established for electrodes in direct contact with neural tissue. Cochlear implant stimulators have much lower charge densities at the stimulable elements by comparison to stimulators in direct contact with neural tissue so a higher value of k is appropriate.

b) A ***Charge Density Limit*** equal to the charge-storage capacity of the electrode material, q, in $\mu C/cm^2$ multiplied by the electrode geometric surface area, A, in cm^2 and expressed formulaically as:

$$\mathbf{Q \leq qA} \qquad \textbf{(9)}$$

where:

Q and A are defined as in Equation (8).

q is the charge-storage capacity or charge density limit of the material, in $\mu C/cm^2$, and is defined as the charge density that causes the material to reach a pre-defined polarization limit (NOTE 1).

For electrodes composed of unroughened platinum, the maximum charge-storage capacity, q, shall not exceed 216 $\mu C/cm^2$. For electrodes with contact material constructed of any material other than unroughened platinum, a charge-storage capacity for the contact material shall be specified and documentation supporting the safety of this value shall be provided.

Most modern cochlear implants use unroughened platinum electrode contacts. It is therefore appropriate to specify a Charge Density Limit for unroughened platinum electrodes that ensures that 1) electrochemical byproducts do not cause harm in the cochlea and 2) the platinum electrodes do not appreciably dissolve.

There are no published *in vivo* data supporting a limit for electrochemistry-induced tissue damage resulting from charge-balanced stimulation. The data that do exist are almost exclusively derived from *in vitro* measurements of electrode polarization and indicate when byproducts first start to form (the so-called "water window"). The actual charge density level for the onset of damage is likely to be considerably higher than the charge density level at which byproducts first start to form, because it is unclear what quantity of byproduct production is likely to cause tissue damage. For example, the charge density level at which gas generation begins is much higher than the charge density level derived from the water window concept for the onset of byproduct production (Rose and Robblee, 1990). The *in vitro* electrochemistry literature predicts that byproducts will begin to form at a charge density of anywhere from 100 $\mu C/cm^2$ (Rose and Robblee, 1990) to 500 $\mu C/cm^2$ (Brummer and Turner, 1977) for cathodic first pulsing. (Note that Brummer and Turner [1977] published the value of 350 $\mu C/cm^2$ calculated in real area, which is converted here to 500 $\mu C/cm^2$ calculated in geometric area.) In a real cochlear implant, byproducts must migrate through a volume containing intrascalar fluid, a possible scar tissue capsule, and modiolar bone if they are to damage the nerve. The *in vivo* charge density limits are therefore likely to be significantly higher than the *in vitro* limits.

There are very limited *in vivo* data on electrode dissolution resulting from charge-balanced stimulation. Platinum dissolution has been shown to be much lower in protein-containing solutions as compared to saline (Robblee et al., 1980), because the platinum appears to be protected by the protein layer that forms on its surface. Robblee et al. (1983) investigated platinum levels in tissue surrounding electrodes during acute *in vivo* stimulation. Here, at charge density levels up to 100 μC/cm^2, platinum was initially detected in the tissue surrounding the electrode; and, as the experiment progressed, platinum started to diffuse further from the electrode interface. Although there is recent evidence from explanted cochlear implants of both platinum electrode corrosion and histopathological evidence of platinum-containing particles (Nadol et al., 2014; Clark et al., 2014), conclusive safety implications of these findings are presently unknown.

The value specified here of 216 μC/cm^2 for the charge capacity of unroughened platinum is a value consistent with values used by early researchers (Biegler et al., 1971). It represents a value in the low-to-middle of the range for published charge capacities of unroughened platinum and is probably conservative for the reasons mentioned above. The specific charge density level of 216 μC/cm^2 was obtained by calculating the highest charge density allowed by the charge and charge density limit (assuming k = 1.75 and a real electrode area of approximately 0.0012 cm^2) from among the approved cochlear implant systems currently on the market at the time of writing of this standard.

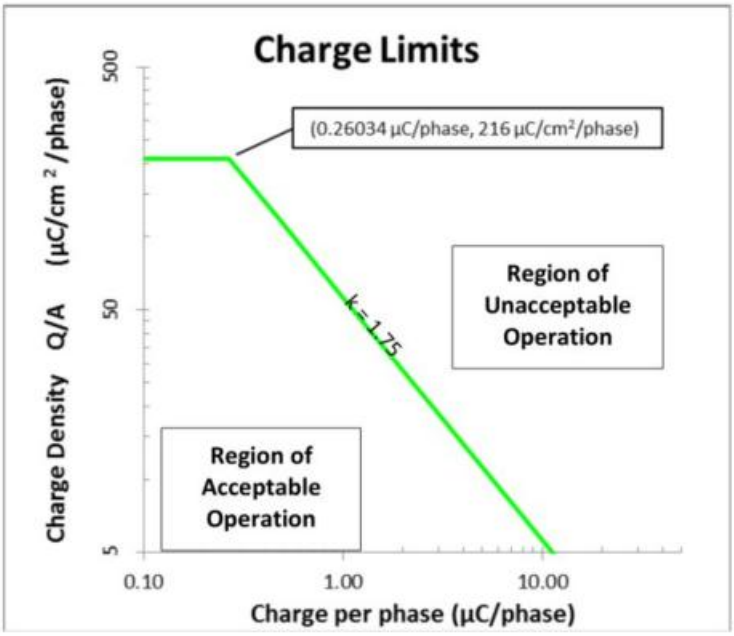


Figure 13—Maximum stimulation limits for charge-balanced, biphasic pulses plotted as a function of charge per phase (x axis) and charge density per phase (y axis) for k = 1.75 and a maximum charge density of 216 μC/cm^2

Because of the limitations of the charge-limit model, alternative values of "k" and maximum charge densities higher than 216 μC/cm^2 may be used if an acceptable justification is provided, including animal data.

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

Compliance will be verified by inspection of the risk analysis and the required risk mitigations, including review of the manufacturer's verification test procedures and test results.

The manufacturer shall demonstrate compliance to this section.

NOTE 1—Manufacturers should use electrochemical methods similar to those presented in the literature (e.g., Rose and Robblee, 1990) to determine the charge capacity of any new materials or platinum roughening process. Essentially, these methods apply a known amount of charge to a known area of the material and determine the polarization voltage that occurs on the material with respect to the electrolyte. The charge level that causes a polarization beyond the water window (roughly + 800 mV and – 600 mV vs. a reference Ag/AgCl electrode) is then

defined as the charge capacity of that material. The limits obtained in this way can vary with a number of factors, including electrode size and shape, electrolyte composition, stimulation phase duration and repetition rate, and charge recovery method (see Section 5.9.4). Manufacturers should take care to establish the limit using conditions similar to those likely to be encountered in the field. The phase durations used should be representative of the phase durations likely to be used in the field under high charge conditions (e.g., 200 µs), because most cochlear implant systems have limited peak-current capacity with realistic electrode impedances. Therefore, to achieve stimulation at the charge capacity limits of the electrodes, long phase durations must be used. These are the phase durations that should be used to determine the charge capacity because they are the phase durations that will be used in practice to deliver high charges. The phase durations used for more typical, lower charge-capacity recipients are usually smaller (e.g., 25 µs) and should not be used in testing, despite being more commonly used in clinical applications.

NOTE 2—There is a lack of chronic, *in vivo* data available to assist with setting safe charge-injection limits for neural stimulators generally and for cochlear implants in particular. One reason for this lack of data is that a good animal model is needed to properly simulate the disease state that leads to the need for high charges (e.g., severe atrophy of the auditory nerve, extreme otosclerosis). An appropriate model should also account for realistic current flow pathways in the cochlea. These are areas where research is required.

NOTE 3—At the time of this writing, a recent *in vitro* study using custom-made electrodes and passive capacitive charge recovery suggests that at least some degree of platinum dissolution occurs for both charge-imbalanced and charge-balanced stimuli delivered at charge density levels below the prescribed limits; and, in fact, the amount of platinum release appears less for charge-imbalanced as compared to charge-balanced biphasic waveforms (Kumsa et al., 2016). These findings highlight the need for additional validated *in vivo* studies of cochlear electrical stimulation to provide greater certainty regarding safe stimulation levels and waveforms.

17.4 Phase duration requirements

The minimum phase duration applied by the implant system when applying pulsatile stimulation shall be 5 µs. There is no requirement limiting the maximum phase duration of the implant system, provided that the maximum charge density and charge requirements of Section 17.3 are met.

No maximum phase duration is specified in this standard because for a given constant charge, the potential damage from both exceeding the charge and charge density limit and from electrochemical byproducts is believed to be less severe for long phase durations than for short phase durations. In terms of charge and charge density, long phase durations are known to be less efficient in recruiting nerves than are short phase durations for a given constant charge (based on the ubiquitous strength/duration curves available for all neural populations). Because neural recruitment is less efficient at longer phase durations, it follows that damage will be less for longer phase durations. However, because hydrogen plating and oxidation reactions of the metal–electrolyte interface are time-dependent processes during charging, longer pulse widths allow higher electrode charge capacity per pulse, particularly *in vivo* (Rose and Robblee, 1990; Leung et al., 2015).

The manufacturer shall demonstrate compliance to this section.

17.5 Stimulation waveform requirements

The stimulation waveform must ensure that the charge transfer is balanced (e.g., zero net charge delivered by one stimulation event) to avoid a net buildup of charge in the neural tissue. If the net charge delivered by a single stimulation waveform is not zero, then stimulation using trains of sequential pulses can result in large cumulative charge delivery across an electrode interface over time. This will drive the operating point of the electrode toward the “water window” and likely result in generation of electrochemical products that might be harmful for tissue.

Waveforms other than biphasic pulses, including asymmetrical pulses (see NOTE), might be acceptable, provided that the charge balance is maintained and safety is demonstrated. In all cases, the requirements of Sections 17.2 and 17.3 shall be met. For multi-phasic stimulation waveforms for which a single phase is not well defined (see Figure 14), the manufacturer shall provide justification for the safety of the stimulation based on quantitative parameters of the stimulus waveform (e.g., the electrical power delivered by the electrode over a given time).

In addition, the manufacturer shall describe how the overall stimulator design, including the stimulation waveform and other provisions enumerated in Section 5.9 (e.g., coupling capacitors, shorting of electrodes between stimulation pulses, bleeder resistors) work to ensure no net buildup of charge in the tissue.

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

The manufacturer shall demonstrate compliance to this section.

NOTE—Some examples of symmetrical and asymmetrical stimulation waveforms that meet the charge-balancing requirement are shown in Figure 14. These are examples only and do not represent all possible charged-balanced stimulation waveforms. Symmetrical waveforms, such as biphasic pulses, are preferred but even these waveforms might not be sufficient to ensure absolute reversible charge balance due to complexity of electrochemical reactions at the electrode–tissue interface.

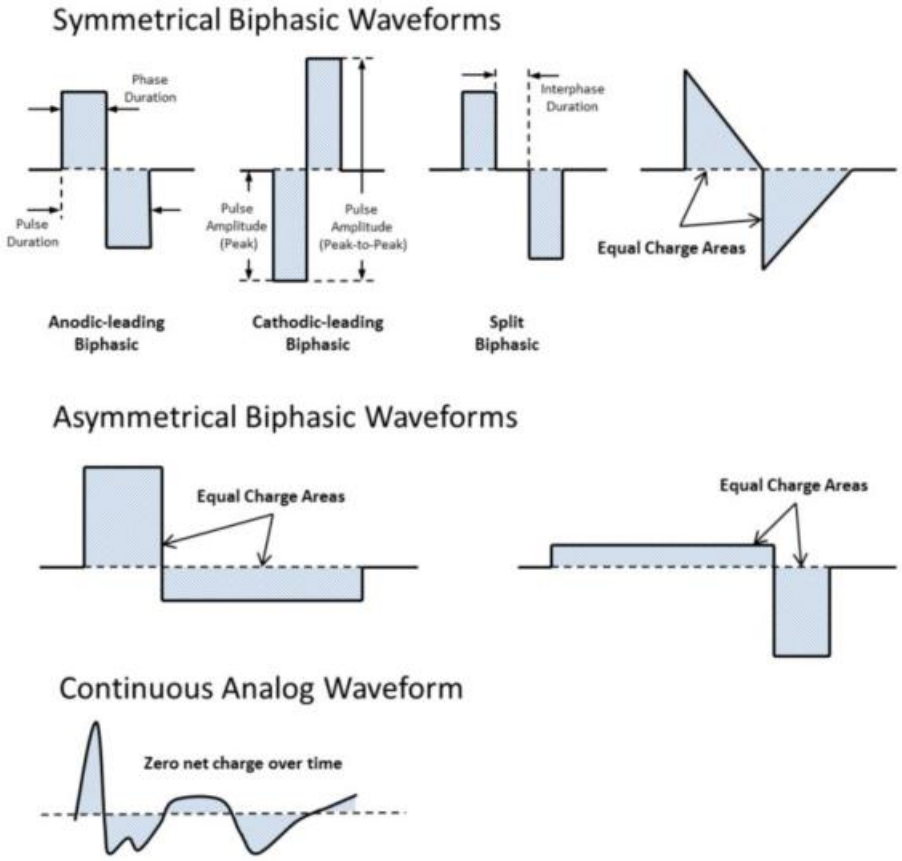


Figure 14—Examples of possible symmetrical and asymmetrical stimulation waveforms that meet the charge-balancing requirement

18 Safety of implantable energy sources

18.1 Documentation on implanted energy source

If the implant system has an implantable energy source, the accompanying documentation shall include information about the lifetime of the energy source, both when the device is adjusted to the nominal clinical settings specified by the manufacturer and when adjusted to the worst-case conditions.

Manufacturer shall demonstrate compliance to this section.

NOTE—At the time of writing of this standard, available cochlear implant systems do not have implantable energy sources. Future implant systems are likely to have rechargeable, implantable batteries. When estimating the lifetime of the energy source for normal clinical settings and worst-case conditions, the manufacturer should take the

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

following parameters into consideration: the battery operating time for a single charge, the total number of recharge cycles, and the charging time.

19 Safety from heat sources

19.1 Thermal limit on outer surfaces of implantable parts

The temperature of outer surfaces of implantable parts of the cochlear implant system shall not exceed 2 °C higher than 37 °C (the normal temperature of the body) when implanted and when the cochlear implant system is operating normally or under any single-fault condition or persistent fault-generating failure mode (see Section 20.3), unless the manufacturer demonstrates that a transient, higher temperature rise is justified based on an analysis of the duration of the temperature rise and its effect on adjacent tissue; an example is CEM43 analysis (Dewhirst et al., 2003). In any case, the manufacturer must provide a method for mitigating against sustained temperature increases greater than 2 ºC.

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

Compliance will be verified by inspection of a design analysis provided by the manufacturer. The design analysis shall be supported by the manufacturer’s calculations and data from test studies, as appropriate. Identification of a part or component that can fail in this manner should be part of the risk analysis.

Manufacturer shall demonstrate compliance to this section.

NOTE 1—Because of the good thermal contact between the implantable parts of a cochlear implant system and the patient’s tissue, a 2 °C rise on the external surface of the implantable device requires significant power dissipation from the implantable energy source. The actual temperature attained on the surface of the device under specific operating or fault conditions will depend on the patient’s own body temperature, which is the ambient temperature for the implant. The temperature limit set by this part of the standard is lower than the relevant limit in IEC 60601-1:2012 (Section 11.1) because of the increased difficulty of taking corrective action when the source of heat is implanted.

19.2 Thermal limit on outer surfaces of external sound processors

The temperature of outer surfaces of an external sound processor shall not exceed the burn thresholds defined in IEC 60601-1 when the external medical device is in contact with the patient’s skin and operating normally or under any single-fault condition in a 30 °C ambient environment (see Section 20.3), unless the manufacturer demonstrates that a transient, higher temperature rise is justified based on an analysis of the duration of the temperature rise and its effect on adjacent tissue; an example is CEM43 analysis (Dewhirst et al., 2003).

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

Compliance will be verified by inspection of a design analysis provided by the manufacturer. The design analysis shall be supported by the manufacturer’s calculations and data from test studies, as appropriate. Identification of a part or component that can fail in this manner should be part of the risk analysis.

Manufacturer shall demonstrate compliance to this section.

NOTE—Instead of using IEC 60601-1, it is acceptable to use an appropriately designed and validated probe to measure the subsurface skin temperature. A measurement technique that simulates physiological skin/biologic properties may be used as long as it is appropriately designed and fully validated, instead of the equipment specified by IEC 60601-1 to measure the temperature while in contact with simulated skin. If such an instrument is used, temperature limits and durations from Table 24 of IEC 60601-1 shall be adjusted and validated to ensure patient safety.

19.3 Thermal limit on outer surfaces of interfacing equipment

The temperature of outer surfaces of interfacing equipment required for fitting (see Section 5.2.2.4) shall not exceed the burn thresholds defined in IEC 60601-1 when the external medical device is in contact with the patient’s skin and operating normally or under reasonably expected single-fault or misuse conditions in a 30°C ambient environment (see Section 20.3), unless the manufacturer demonstrates that a transient, higher temperature rise is justified based

on an analysis of the duration of the temperature rise and its effect on adjacent tissue; an example is CEM43 analysis (Dewhirst et al., 2003).

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

Compliance will be verified by inspection of a design analysis provided by the manufacturer. The design analysis shall be supported by the manufacturer's calculations and data from test studies, as appropriate. Identification of a part or component that can fail in this manner should be part of the risk analysis.

Manufacturer shall demonstrate compliance to this section.

NOTE—Instead of using IEC 60601-1, it is acceptable to use an appropriately designed and validated probe to measure the subsurface skin temperature. A measurement technique that simulates physiological skin/biologic properties may be used as long as it is appropriately designed and fully validated, instead of the equipment specified by IEC 60601-1 to measure the temperature while in contact with simulated skin. If such an instrument is used, temperature limits and durations from Table 24 of IEC 60601-1 shall be adjusted and validated to ensure patient safety.

19.4 Thermal limit on surfaces of external batteries in contact with skin

The temperature of surfaces of external batteries in contact with skin shall not exceed the burn thresholds defined in IEC 60601-1 (Table 24) when operating under worst-case load conditions in a 30°C ambient environment, unless the manufacturer demonstrates that a transient, higher temperature rise is justified based on an analysis of the duration of the temperature rise and its effect on adjacent tissue; an example is CEM43 analysis (Dewhirst et al., 2003).

This requirement pertains to all body-worn components, including external battery components located during use either behind the ear or at other body locations by means of cable or wireless connections.

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

The test procedure is as follows:

1) Use fresh and fully charged batteries for these tests, and conduct the tests in an oven at 30 °C.

   NOTE—A fresh battery is one that has not been charged or discharged since manufacture, is less than 6 months old from the date of manufacture, and has been stored according to the manufacturer's recommendations.

2) Determine the load that results in the highest surface temperature of the battery. This load could be an impedance that results in the maximum current flow before the battery's internal protection operates. The search for this load value shall commence with a value of less than 100 milliohm, in accordance with IEC 62133 and is known as the worst-case load.
3) Determine the location of the hottest area of the battery that is likely to come in contact with skin under normal use and with the worst-case load determined in Step 2). Describe the determination method in the test report.
4) Measure temperature at the hottest area identified in Step 3).
5) If the battery could be used under a blanket by the recipient of the device, simulate this condition by placing a four-fold folded cotton towel on top of the device. The towel shall have been conditioned to a temperature of 30 °C.
6) Using fresh and fully charged batteries, apply the load determined in Step 2) and monitor the temperature until the battery is fully depleted.
7) Report temperature vs. time behavior under worst-case external load conditions.

Compliance will be verified by inspection of a design analysis provided by the manufacturer. The design analysis shall be supported by the manufacturer's calculations and data from test studies, as appropriate. Identification of a part or component that can fail in this manner should be part of the risk analysis.

Manufacturer shall demonstrate compliance to this section.

NOTE—It is acceptable to use an appropriately designed and validated probe to measure the subsurface skin temperature. A measurement technique that simulates physiological skin/biologic properties may be used as long as it is appropriately designed and fully validated for the test condition to ensure accuracy to simulate the situation, such as when a blanket is placed over the device thereby restricting airflow, instead of the equipment specified by IEC 60601-1 to measure the temperature while in contact with simulated skin. If such an instrument is used, temperature limits and durations from Table 24 of IEC 60601-1 shall be adjusted and validated to ensure patient safety. However, Steps 1) through 7) shall still be followed.

20 Safety from unintended effects caused by the device

NOTE—See also Section 12.13.

20.1 Maintenance of integrity of materials for life of the implantable device

Implantable parts of a cochlear implant system that contact the body tissue shall be designed so that gradual, long-term changes in the materials that might occur within the lifetime of the device shall not cause an unacceptable hazard.

That gradual, long-term changes in materials do not cause unacceptable hazards shall be demonstrated by one or more of the following:

a) Analogy with published data
b) Selection of materials already shown to be stable 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) Use of published procedures for evaluation of materials for implantation. A documented analysis of the experience with the material and its role in the device shall identify any hazards and show that unacceptable hazards have been eliminated.

Manufacturer shall demonstrate compliance to this section.

NOTE—Most active implantable medical devices are designed to have an implanted life of several years. Therefore, tests aimed at obtaining accurate time-to-failure or lifetime information are often impractical. An accepted practice is to reduce the time required to obtain the desired information by changing the environment in which the test is performed (accelerated testing). From the results of such a test, it is possible to draw conclusions about lifetime properties in a more benign environment, provided that the following conditions are true:

a) The failure modes observed in the accelerated environment are the same as those observed under conditions of use; and
b) It is possible with a reasonable degree of assurance to extrapolate from the accelerated environment to the conditions of use.

20.2 Advanced warning of depletion of implantable power source

If the implantable part of an implant system contains within it a source of power, such as a battery, the implant shall include an indicator that gives advance notice of energy source depletion to the clinician and user. It is desirable that exhaustion of the power supply of an implant system does not cause it to cease functioning without previous warning. The warning mechanism provided should not be invalidated by different stimulation strategies that deplete the power source at differing rates. The indicator can be either internal or external; however, it is acceptable for this feature to be an option selectable by the clinician.

Compliance is verified by inspection of a design analysis provided by the manufacturer and supported by the manufacturer's calculations and data from test studies, as appropriate.

Manufacturer shall demonstrate compliance to this section.

20.3 Risk analysis of single-fault conditions

A cochlear implant system shall be fail-safe in that it shall be designed so that the failure of any single component, part, or (if the device incorporates a programmable electronic system) software program shall not cause an unacceptable risk, in accordance with the risk management process specified in ISO 14971.

The hazards caused by possible single-fault conditions and associated with each function of the device shall be identified. For each hazard, the probability of harm shall be assessed by a design analysis that takes into account any hazard control and allows the probability of harm being caused by each fault condition to be evaluated. The design analysis shall be supported by test studies, as appropriate.

Because of the design constraints on practicable devices, the device designer shall preferably lead, but at a minimum be involved with, the risk analysis of hazards associated with single-fault conditions. The methodology for the analysis is set by ISO 14971. The requirement for reliable software in programmable systems is addressed by the methodologies in ISO 14971 and IEC 62304.

For each hazard, the hazard controls incorporated in the device and the assessment of probability of harm shall be documented, together with the design analysis and appropriate test results.

Manufacturer shall demonstrate compliance to this section.

20.4 No unacceptable risk from intended use of active implant

Possible side effects arising from the intended use of a cochlear implant system shall not cause unacceptable risk, in accordance with the risk management process specified in ISO 14971.

The side effects and benefits of the intended use of the device shall be identified, either by reference to current medical practice and demonstrated by analogy or by reference to clinical investigations conducted in accordance with ISO 14155. Side effects shall be listed in warnings (see Section 12.17).

Manufacturer shall demonstrate compliance to this section.

NOTE—Some traditional pharmaceutical clinical investigation criteria might not be applicable to active implantable medical devices (e.g., age distributions and double-blind controls). The scope of any clinical investigation will be restricted by the small available target population and the relatively low incidence of the target pathology.

20.5 Design assurance for removal and reimplantation compatibility

The physical, biological, and geometric properties of the implantable parts of an implant system shall, as far as necessary, be designed to ensure that device removal and replacement with a device from the same manufacturer is not compromised.

Compliance is verified by inspection of a design analysis provided by the manufacturer and, if available, appropriate test and clinical data (e.g., post-market surveillance data related to device replacement).

Manufacturer shall demonstrate compliance to this section.

NOTE—The committee recognized that the lifetime of the currently available implant systems might be shorter than the life expectancy of the patients, especially young children. From an ethical point of view and considering the state of the art, implant system replacement should be possible. During the design process, the manufacturer should consider the following factors that might adversely affect device replacement: compatibility of dimensions and shape, minimization of biological effects, and mechanical robustness to mitigate against breakage of the electrode array and array fragments or contacts being left in the cochlea after explantation.

20.6 Hermeticity testing and compliance

The implantable stimulator case of an implant system intended in normal use to be in contact with body fluids shall provide sufficient hermeticity so that no fluid can infiltrate the stimulator case.

NOTE—The committee recognized that it is desirable for manufacturers and experts to provide assurance that the stimulator case sealing will prevent any contact between components included within the case and body fluids. Such failure could induce electronic dysfunctions of the device, unintended stimulations in the vicinity of the device, and/or unintended biological effects caused by inner non-biocompatible parts (i.e., electronic components) in contact with body fluids.

Fine and gross leak tests shall be conducted on the hermetic casing of the stimulator of an implant system in accordance with EN 13185 and EN 1593. Alternatively, testing may be conducted per MIL-STD-883 Method 1014. If a group A technique is used from the EN 13185 standard, then a gross leak test is not required; and if a group B technique is used, then the gross leak test shall follow the fine leak test. Alternative validated leak test methods capable of detecting leaks in this range may be used. The validation documentation for the test method and device in question shall be included in the regulatory documentation.

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.

Compliance is verified by inspection of the test procedures and results provided by the manufacturer. For the fine leak test, the device leak rate shall not exceed 5×10^{-9} Pa m^3/s. For the gross leak test, no definite stream of bubbles or two or more large bubbles shall not originate from the same point of the stimulator case.

NOTE—The manufacturer should include adequate hermeticity testing in the manufacturing process.

20.7 Implantable device internal moisture content

The stimulator case of an implant system intended to be in contact with body fluids during normal use shall ensure that the internal moisture content in the hermetic cavity housing the electronics is either less than 5,000 ppm over the useful life of the device (see Section 6.2) or less than an alternative moisture content specification over the useful life of the device as chosen by the manufacturer. This alternate moisture content specification shall be based on engineering analysis and supporting data. This value shall be established to ensure that devices do not fail within the useful life period stated by the manufacturer, including storage and shipping prior to implantation. The engineering analysis and data for an alternate value shall be included in the information submitted to the regulatory body.

For design and manufacturing validation activities, test samples shall be selected in accordance with Section 8.6. The sample size category for this test is "high." Samples shall be taken at the end of the complete manufacturing process and represent the final shippable device configuration. Residual gas analysis or a similar validated test shall be conducted on the hermetic casing of the stimulator of an implant system. The validation documentation for the test method and device in question shall be included in the regulatory documentation. The manufacturer shall include adequate hermeticity testing in the manufacturing process to demonstrate that the moisture content specification of <5,000 ppm is maintained through the shipment process.

Compliance is verified by inspection of the test procedures and results provided by the manufacturer. If the manufacturer uses an alternative water vapor acceptance level, the manufacturer shall demonstrate that in an open condition no failures of the device functionality were observed.

21 Safety and device immunity during magnetic resonance imaging

21.1 Conditions for safe MRI usage

Implantable components of a CI system and any non-implantable components and accessories labeled MR Conditional shall be designed and constructed so that no permanent damage to the device or unacceptable risk to the patient can be demonstrated during or following exposure to the MR environment specified in the MR Conditional labeling. Magnet weakening or magnet polarity reversal is acceptable, provided that after exposure to the MRI system, the attachment force provided by an external magnet continues to meet the specified minimum attachment force.

Implantable parts of a CI system that are declared by the manufacturer to be MR Conditional shall be identified. The manufacturer shall declare the conditions (including the specific magnetic field strengths) under which a patient with the MR Conditional components can be safely scanned (see Section 12.5). Labeling shall include specification in the product data sheet of the acceptable MRI field strength as well as all other conditions under which a patient with a CI

system containing MR Conditional components can safely be scanned (see Section 12.1). The declaration shall include a statement of the risks of demagnetization and image distortion and instructions for the safe performance of MRI investigations, if applicable. All non-implantable components and accessories labeled MR Conditional or MR Unsafe shall be marked directly, when size permits, with either the MR Conditional or MR Unsafe icon, respectively. Section 12.25 describes specific labeling requirements regarding MRI safety and immunity claims.

When a patient with an implant system enters the MR environment, the following are possible sources of harm:

a) Magnetically induced displacement force and torque
b) Gradient-induced vibration
c) Radio-frequency induced heating
d) Gradient-induced heating
e) Unintentional device output
f) Weakening of implant magnet
g) Implant damage
h) Imaging artifact

NOTE—Imaging artifact is not a source of immediate harm to the patient; however, image artifact could result in the misinterpretation of test results or in a treatment delay that might lead to harm to the patient.

For an implantable part of a CI system intended to be used in patients who undergo magnetic resonance scanning in non-multi-transmit head or body coils operating in the quadrature mode and generating a circularly polarized RF field, the requirements of ISO/TS 10974 shall be used as a guideline. During testing in the MR environment, the device under test shall not be powered and not in operation.

NOTE 1—This section does not apply to devices that are not labeled MR Conditional.

NOTE 2—Other MR environments will require manufacturer evaluation by similar or other means.

None of the test results shall indicate an unacceptable risk to the patient.

After each test, the device shall operate as intended according to its MR Conditional labeling and conform to the acceptance criteria listed in the manufacturer's specification. Device samples or subassemblies used for testing shall meet all manufacturer's specifications relevant to these tests.

Each of the potential sources of harm shall be investigated as described in the following subsections.

Manufacturer shall demonstrate compliance to this section.

21.2 Displacement force and torque acting on the implantable component

The implantable part of an implant system shall not cause an unacceptable risk to the patient as a result of mechanical forces that can occur during MRI scanning.

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.

21.2.1 Magnetically induced torque

Torque is exerted on the implant magnet, which acts to align the magnet so that its magnetization is parallel to the static magnetic field B_0.

Test Method: Measure the B_0-induced torque acting on the implant and parts thereof according to the method described in ASTM F2213 (referenced in ISO/TS 10974) or any equivalent method.

Acceptance criteria: No risk to the patient due to magnet flipping out of pocket is acceptable. Magnetically induced (B_0-induced) torque shall be less than the worst-case gravity-induced torque, which is defined as the product of the weight of the device and the longest linear dimension, or less than a greater specified value supported by a

scientifically based rationale that demonstrates that torque does not cause unacceptable risk to the patient or affect the functionality of the device following the test.

21.2.2 Magnetically induced displacement force

A magnetically induced displacement force acts to pull ferromagnetic and paramagnetic elements of the implant into the bore of the MRI system.

Test Method: Magnetically induced forces acting on the implant shall be measured according to the method described in ASTM F2052 (referenced in ISO/TS 10974) or any equivalent method.

Acceptance criteria: Magnetically induced force shall be less than the weight of the device or less than a greater specified value that is supported by a scientifically based rationale that demonstrates that the force does not cause unacceptable risk to the patient or affect the functionality of the device following the test.

Any rationale should address factors including the potential for patient harm associated with strength of tissue, weight of the device, and forces acting on the implant.

The labeling should include the specific field strength and the maximum spatial field gradient to which a patient with the device can safely be exposed during an MRI.

21.3 Gradient-induced vibration

Gradient fields of MR scanners induce eddy currents in the device. The magnetic moments of these eddy currents interact with the MR scanner's static magnetic field, resulting in vibration of the device. Therefore, the test needs to be performed with the worst-case clinically relevant gradient fields acting orthogonally to the different surfaces of the device in clinically relevant orientations.

Unacceptable risk to the patient shall not result from gradient-induced vibrations of the implantable part of an implant system. The implantable part of an implant system shall not be damaged through mechanical forces arising from gradient induced vibrations.

21.3.1 Harm to the patient

Unacceptable risk to the patient shall not result from gradient-induced vibrations of the implantable part of an implant system.

Compliance is verified if gradient-induced vibrations of the implantable part of an implant system are considered to not cause unacceptable risk to the patient.

21.3.2 Damage to the implant

The functionality of the implantable part of an implant system (as defined in the MR Conditional labeling) shall not be affected by mechanical forces arising from gradient-induced vibrations. Gradient-induced vibrations can be measured according to the test methods described in ISO/TS 10974.

Compliance is verified if gradient-induced vibrations do not affect the functionality of the device.

21.4 Radio-frequency-induced heating

The implantable part of an implant system shall not generate excessive tissue heating during MRI scanning.

The test shall be performed according to ISO/TS 10974.

Test samples shall be selected in accordance with Section 8.6.

RF induced heating of adjacent tissue(s) shall not cause unacceptable risk. This heating value shall be below a limit supported by scientific rationale linked to clinical significance for the adjacent tissue(s). If the temperature rise is ≤ 2 °C, then no further scientific rationale is needed.

Label the device according to the maximum modeled specific absorption rate (SAR) value permissible to limit damage to surrounding tissue due to the heating of the device electrodes.

Acceptance criteria: In order to stay below any threshold for neural tissue damage, the radio-frequency-induced heating shall not exceed a 2°C change, or a higher value for which a scientific rationale and/or validated model predictions are given.

Compliance is verified if the acceptance criteria for radio-frequency-induced heating are met.

21.5 Gradient-induced heating

The implantable part of an implant system shall not generate excessive tissue heating during MRI scanning.

The test shall be performed according to ISO/TS 10974.

Test samples shall be selected in accordance with Section 8.6.

Gradient-induced heating of adjacent tissue(s) shall not cause unacceptable harm. This heating value shall be below a limit supported by scientific rationale linked to clinical significance for the adjacent tissue(s). If the temperature rise is ≤ 2 °C, then no additional scientific rationale is needed.

Compliance will be verified by inspection of the manufacturer's test data and report.

21.6 Unintentional device output

The implantable part of an implant system shall not generate output that poses unacceptable risk to the patient during MRI scanning.

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

The test methods described in ISO/TS 10974 shall be used to assess the unintentional output.

Alternatively, a test procedure may be used as follows:

1) The implantable part of the implant system shall be completely immersed in a gelled phantom (per ASTM F2182). The implant shall be oriented within the MRI scanner in order to evaluate the worst-case voltage induction. The following implant orientations shall be used:
   - *i.* *Induction caused by the gradient fields:* The device should be placed in the maximal dB/dt location. This location shall be determined using a three-plane search coil. In order to maximize the induced effect, the electrodes are placed in a loop configuration and oriented with the normal vector of the loop surface aligned with the dB/dt vector. The sequence used for this test has to reach the maximal slew rate permitted by the scanner. If possible, the RF field shall be switched off.
   - *ii.* *Induction caused by the RF field:* Voltage induction due to the RF field is caused by two mechanisms: B1-field loop induction and E1-field antenna effect. In order to evaluate these effects, two tests shall be performed:
     1. To assess the B1-field loop induction, the device shall be placed at the maximum B1-field location. The electrodes shall be placed in a loop configuration and shall be oriented with the normal vector of the loop surface aligned with the dB/dt vector.
     2. To assess the E1-field antenna effect, the device shall be placed in the maximum E1-field location. The electrodes shall be placed tangential to the E1 field.

     NOTE—The maximal B1 and E1 locations may be determined using numerical simulation. The sequence used for the test has to reach the maximum RF pulse permitted by the scanner.

2) The voltage signal induced between the reference electrode and the most distal active electrode of the implant shall be measured. Therefore, short and twisted measurement cables shall be attached to the corresponding electrode leads at the feed-throughs of the implant. An electronic circuit shall transform the measured voltage into an optical signal, which is then sent through a fiberoptic cable outside the MRI environment. The measurement setup shall be adjusted for frequencies of up to a minimum of 20 kHz and

its influence on the measured voltage shall be assessed. The electronics of the measurement system shall be small enough not to disturb the MRI fields.

NOTE—A possible probe design is described in Barbier et al. (2014).

3) The resulting unintentional device output (current or charge flow through the implant) due to the MRI-induced voltage signal shall be derived from the voltage–current characteristics at the stimulator output of an unpowered implant.
4) The resulting unintentional device output (amplitude, charge, and morphology of the signal) shall be assessed in terms of patient safety.

Compliance is verified if the unintentional output remains within the safe stimulation charge limits specified in Section 17.3.

21.7 Implant magnet weakening

An important condition of device functionality for cochlear implant devices with a magnetic internal component is that the magnet will not be demagnetized or compromised by exposure to an MRI system. For a device with an included magnet, in addition to addressing the issues in Section 21.8, it should be demonstrated as part of device functionality that the MRI system magnetic field does not unacceptably affect the intended operation of the implant's magnet. An acceptance criterion, with a scientifically based rationale for including required magnetic attachment force, shall be provided.

The implant magnet shall not weaken during MRI scanning to an extent that does not allow sufficient attraction of the external coil to the implant. Magnet polarity reversal is acceptable, provided that the external headpiece can remain attached. Test samples shall be selected in accordance with Section 8.6. The sample size category for this test is "medium" where the implant magnet is not replaceable and "low" where the magnet is replaceable.

The test procedure is as follows:

1) Fully magnetized magnets shall be placed inside the scanner at defined angles with respect to the static MRI field. The angles shall be chosen to represent both typical values and worst-case values.
2) Because any magnet weakening caused by a reverse external magnetic field occurs instantaneously, exposure to the magnetic field for a few seconds is sufficient.
3) Weakening of the implant magnet shall be measured and documented in percent after initial exposure and after ten repeated exposures to the same initial field level.
4) Product labeling shall state the expected percentage of magnet weakening after one MRI exposure and after ten MRI exposures, and it shall describe the MRI conditions under which implant magnet weakening can be minimized. Product labeling shall also provide information about whether an alternative fixation means (e.g., a stronger or an adjustable magnet for the non-implantable part) is available. A rationale shall be included to explain why ten exposures are sufficient to represent a worst case for the number of exposures to an MRI scanner static magnetic field that could occur during the implant life.

Compliance is verified if product labeling contains information about possible implant magnet weakening, including the expected percentage of magnet weakening after one and after ten exposures and the conditions under which implant magnet weakening can be minimized. A reduction in the implant magnet strength is acceptable, provided that it meets the minimum specified strength for magnetic attachment force of the non-implantable component.

21.8 Maintenance of implant functionality during and after MRI scanning

The implantable part of an implant system shall operate as intended according to the MR Conditional functionality specified in the MR Conditional labeling and shall not be damaged during MRI scanning. Device performance over the useful life shall not be degraded, either during (if labeled) or after scanning. The electrical link between external and implant components and the electrical stimulation output shall be checked before and after the MRI exposure in order to verify that device performance is not degraded following MR exposure. The verification should be performed within 30 minutes of the MRI exposure for a single implant or within one hour if two devices were exposed sequentially.

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

The MR Conditional functionality of the implant shall be tested according to ISO/TS 10974 including for the static magnetic field, gradient field, RF field, and combined field.

Compliance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (see Section 8.7).

21.9 Imaging artifact

The product labeling shall contain information about the size of MRI image artifacts for each field strength specified as MR Conditional by the implant manufacturer.

The test procedure shall be performed according to ASTM F2119.

Product labeling shall provide the head image in axial view, with the slice showing the largest image artifact, and shall describe the scan parameters. For implants with removable magnets, this information shall be provided for the implant both with and without the magnet.

NOTE—An image of the artifact using an adult head might be a helpful option for the radiologist.

Compliance is verified if product labeling contains information about the size of the imaging artifact (see Section 12.25.3(i)).

22 Device immunity to external stresses caused by medical treatment and procedures

During verification testing against sections within this standard, it is permissible to test only the functions of the device being assessed for compliance with the specific section.

NOTE—High-level X-ray and gamma radiation can affect electronics and has been shown to cause effects in active implantable medical devices.

At the time of the writing of this standard, there are no specific requirements for immunity or warnings related to high-level x-ray or gamma radiation.

22.1 Requirements for immunity

22.1.1 Immunity to diagnostic ultrasound energy

The implantable components shall be designed and constructed so that no irreversible change will be caused by exposure to diagnostic levels of ultrasonic energy.

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

The test protocol to show compliance with this requirement is described in Section 22.2.1.

The acceptable level of diagnostic ultrasonic energy shall be specified in the labeling in the product data sheet (see Section 12.1).

Manufacturer shall demonstrate compliance to this section.

NOTE—This requirement addresses only exposure to diagnostic ultrasound. Exposure of a cochlear implant system to higher, therapeutic levels of ultrasound is addressed by a requirement for a warning notice (see Section 12.7). Other related warnings of potential damage caused by current flow from medical treatments or procedures and by therapeutic ionizing radiation are addressed in Sections 12.6 and 12.80, respectively.

22.1.2 Immunity to therapeutic ionizing radiation

The implantable components shall withstand the levels of therapeutic ionizing radiation specified by the implant manufacturer.

The test protocol to show compliance with this requirement is described in Section 22.2.2. Three test samples shall be tested.

The acceptable level of ionizing radiation dose shall be specified in the labeling in the product data sheet (see Section 12.1).

Manufacturer shall demonstrate compliance to this section.

NOTE—Examples of ionizing radiation include, but are not restricted to: radio waves, microwaves, visible light, X-rays, gamma rays, beams of subatomic particles (e.g., protons, alpha particles, beta particles, neutrons, and positrons) as well as heavier particles (e.g., carbon ions). For example, such ionizing radiation could be used in the curative or adjuvant therapeutic treatment of tumors in the brain or head.

22.1.3 Immunity to applied currents during surgery

The implantable part of an implant system shall be designed so that stray, high-frequency current flowing through the patient during surgical diathermy does not permanently affect the device, provided that the implant system does not lie directly in the path between cutting and return (RF earth) electrodes of surgical diathermy devices. (See also Section 12.6 requirements regarding warnings.)

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

The test protocol to show compliance with this requirement is described in Section 22.2.3.

Guidance shall be provided to the clinician regarding acceptable surgical risks related to applied currents (See Section 12.6).

Manufacturer shall demonstrate compliance to this section.

22.1.4 Immunity to stresses during defibrillation

Parts of a cochlear implant system intended to be implanted in the torso shall be designed so that defibrillation of the patient will not permanently affect the device, provided that the defibrillator electrode does not come into direct contact with the implanted part.

NOTE—In general, it is not possible to provide absolute immunity for active implants containing semiconductors. Damage that is not apparent could reduce the lifetime of semiconductor components, hence the requirement for warnings in Section 12.6.

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

The test protocol to show compliance with this requirement is described in Section 22.2.4.

Manufacturer shall demonstrate compliance to this section.

22.2 Testing for immunity

NOTE—See also Sections 12.5, 12.6, 12.7, and 12.8.

22.2.1 Testing for immunity to diagnostic ultrasonic energy

This section specifies acceptance testing to verify compliance with the requirements for immunity to diagnostic ultrasonic energy specified in Section 22.1.1.

The test procedure shall be performed in accordance with ISO 14708-1.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

22.2.2 Testing for immunity to therapeutic ionizing radiation

This section specifies acceptance testing to verify compliance with the requirements for immunity to therapeutic ionizing radiation specified in Section 22.1.2.

The test procedure is as follows:

1) Irradiate three samples of the implantable component with photon radiation in 5-Gray doses to the maximum cumulative dose specified by the manufacturer.
2) Deliver the irradiation at 24 hour intervals, at least four times per week.
3) After each exposure, functionally test the test sample to verify compliance with the requirements of the manufacturer's design verification test (Section 8.7).
4) If the test sample is determined to be functional, apply a further dose and repeat the test.

The manufacturer shall state the median cumulative dose of the three samples for which the samples passed the functional test. The labeling statement (Section 12.8) shall specify a safety margin of 20 % of this dose.

NOTE— It is recognized that current and future cochlear implant designs are likely to continue to have a degree of susceptibility to degradation or malfunction following exposure to therapeutic ionizing radiation. Furthermore, it is recognized that cochlear implant patients need not be disadvantaged when therapeutic radiation treatment is required. Although radiation treatment might be targeted over (or close to) the implanted part, the majority of treatments will be targeted at other locations. In the latter situation, exposure to radiation scatter is likely to be the main concern. In keeping with good clinical practice, a patient-specific treatment plan with implant avoidance should be generated and considered. Device-specific acceptable dose limits should be considered as part of the overall benefit–risk profile of the treatment plan.

Literature reports of irradiation testing of some cochlear implants (Baumann et al., 1999; Gossman et al., 2011; Klenzner et al., 2005; Ralston et al., 1999) indicate that although current designs have a limited degree of "hardness" to the effects of ionizing radiation, no device can be designed and manufactured to be totally immune. Although manufacturers need to demonstrate a level of immunity of their designs to ionizing radiation, a minimum radiation "hardness" level would result in unfair discrimination. Consequently, the approach is to define an irradiation test method, based on common radiation treatment patterns (fractional accumulated dosage), and test until failure. The manufacturer declares the maximum level of accumulated dose after which the device will continue to function normally. Labeling on the basis of this test enables clinicians to judge whether an intended pattern of radiation therapy is likely to permanently affect the functionality of the implanted part.

22.2.3 Testing for immunity to applied currents during surgery

This section specifies acceptance testing to verify compliance with the requirements for immunity to applied currents during surgery specified in Section 22.1.3.

The test procedure is as follows:

1) Use a signal generator with an output impedance of 50 Ω (R1). The test signal frequency shall be 500 kHz sinusoid and the open loop test signal amplitude shall be 20 V_{pp}.
2) Switch off the implantable stimulator component.
3) Connect each output of the implantable part, via a resistor (R2-Rn) of 4.7 kΩ, to a common point, and connect that point to the output of the signal generator (see Figure 15).
4) Connect the reference electrode of the implantable part of the implant system, via a 100 Ω resistor (R3), to the ground of the signal generator.
5) Apply the test signal in ten bursts each for a duration of 1 s, allowing a recovery period of 5 s between bursts.

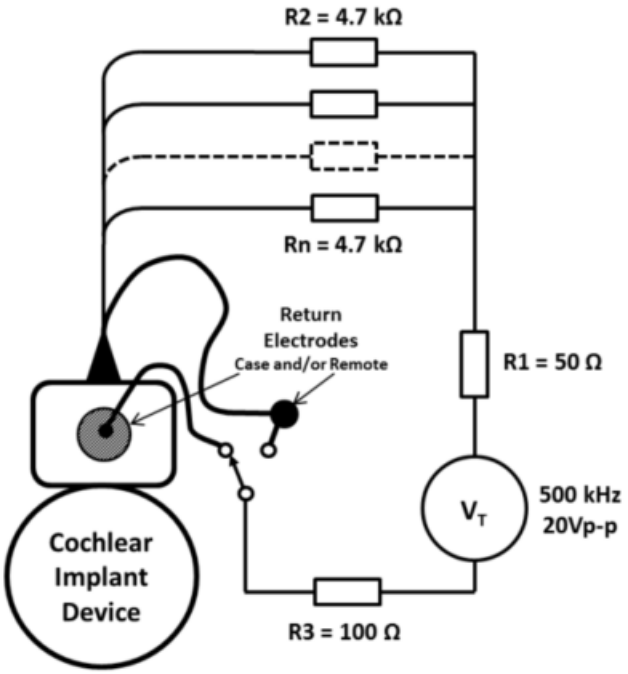


Figure 15—Test setup for proof of protection from high-frequency currents caused by surgical equipment

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

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

NOTE—The test verifies a degree of immunity from high-frequency electrical currents arising from surgical diathermy. The test frequency of 500 kHz was selected as typical of the majority of electrosurgical equipment. The selected amplitude of 20 V_{pp} to test the protection of the device was adapted from the pacemaker standard, EN 45502-2-1. The load resistor of 4.7 kΩ was chosen to reflect the impedance of the neural tissue interface in the cochlea. During the test, the implant system should be switched off. This test does not provide complete coverage, because the voltages picked up during exposure to surgical diathermy are variable and dependent upon the distances between the diathermy electrodes and any conductive part of the implant system or its electrode array.

22.2.4 Testing for immunity to external defibrillation stresses

This section specifies acceptance testing to verify compliance with the requirements for immunity to external defibrillation stresses specified in Section 22.1.4.

The test procedure is as follows:

1) Use a defibrillation pulse generator consisting of an RCL circuit (Figure 16), with:

   C = 330 µF ± 16.5 µF (± 5 %)
   L = 13.3 mH ± 0.13 mH (± 5 %)
   R_L and R_G = 10Ω ± 0.2Ω (± 2 %)

   where:

   R_L is the resistance of the inductance, in ohms;
   R_G is the resistance of the defibrillation pulse generator, in ohms;

V_{test} is the output voltage, in volts.

The maximum pulse amplitude of the output voltage (V_{test}) at the output of the defibrillation pulse generator, across R_G, shall be 140V ± 7V (± 5 %).

2) Ensure that the inductor is not magnetically saturated during the pulse.
3) Identify each conducting part, other than a metallic case, that could come into contact with body tissue.
4) Connect the defibrillation pulse generator through a 300Ω ± 6Ω (± 2 %) resistor (Figure 16) between each of the conducting parts in turn and the metallic case. If the body of the device is enclosed in a metallic case covered with an insulating material or is constructed of insulating material, immerse the body of the device in a metallic jar filled with physiological 9 grams/liter (g/l) saline solution and make the case connection to the jar.
5) Test each conducting part by applying a sequence of three voltage pulses of positive polarity at 20 s (+2 s/-0 s) intervals.
6) After an interval of 60 s (+2 s/-0 s), repeat the test with pulses of negative polarity (Figure 17).

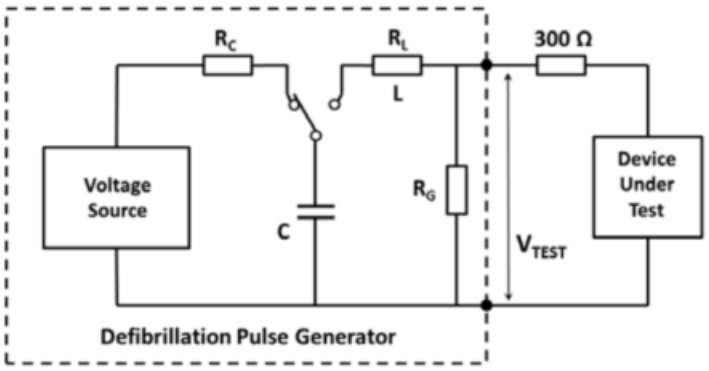


Figure 16—RCL circuit for defibrillation test for active implantable medical device

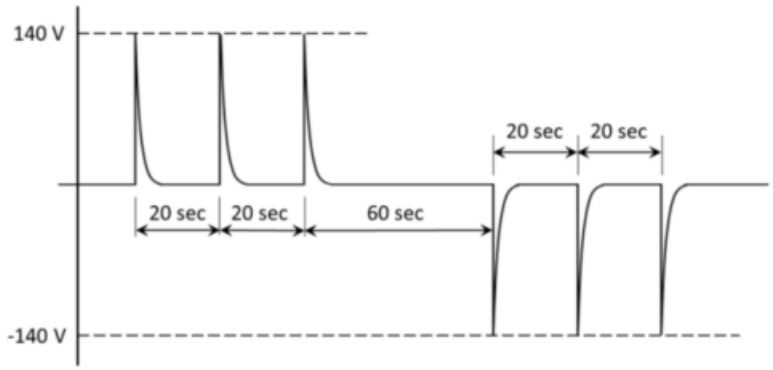


Figure 17—Form of V_{test} pulses used in defibrillation test

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

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

NOTE—The circuit details in Figure 16 are specified so that the energy delivered to the device, when it is directly connected to the test equipment through the 300 Ω resistor, is similar to the energy delivered to the device through the stimulating electrode or other interconnecting conductor, such as a ground electrode, when the subject is defibrillated using external defibrillation paddles. The specified test avoids the use of the high voltages delivered directly by defibrillator paddles. Defibrillation attempts often have to be repeated and the polarity of the signal introduced cannot be restricted. This subsection is intended to set a practical level of protection so that, in most cases, defibrillation will not damage an active implantable medical device. In general, it is not possible to provide absolute immunity for active implants containing semiconductors. Damage that is not apparent could cause reduce the lifetime of semiconductor components, hence the requirement for warnings in Section 12.6.

Currently available cochlear implant systems do not have implantable parts in the torso. It is conceivable that parts of future devices might be implanted in the torso (e.g., a battery or a recharging coil).

23 Device immunity to stresses of mechanical forces

23.1 Requirements for immunity

23.1.1 Immunity to vibration stresses during normal use and handling

The implantable part of the implant system shall be constructed to withstand the mechanical forces that might occur during normal conditions of use, including handling during the time prior to implantation.

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

The test protocol to show compliance with this requirement is described in Section 23.2.1.

Manufacturer shall demonstrate compliance to this section.

23.1.2 Immunity to minor mechanical impact stresses during implantation handling

The implantable part of an implant system shall be constructed so that minor shocks caused by handling during the implantation procedure do not damage the device.

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

The test protocol to show compliance with this requirement is described in Section 23.2.2.

Manufacturer shall demonstrate compliance to this section.

23.1.3 Immunity to mechanical impact stresses during normal use, including trauma

The implantable part of the implant system shall be constructed so that impacts experienced during normal use do not damage the device.

NOTE—Normal use is considered to include cases in which the device housing receives direct mechanical impact through the skin because of falls or collisions by the user or incidental direct external strikes delivered to the device (e.g., by bats or balls). This requirement applies only to implantable parts that are exposed to mechanical impact because of their location when implanted.

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

The test protocols to show compliance with this requirement are described in Section 23.2.3.

Manufacturer shall demonstrate compliance to this section.

23.1.4 Immunity of implantable antenna coil to mechanical impact stresses

The implantable antenna coil of the implant system shall be constructed so that impacts experienced during normal use do not damage the device.

NOTE—Normal use is considered to include cases in which the device coil receives direct mechanical impact through the skin because of falls or collisions by the user or incidental direct external strikes delivered to the device (e.g., by bats or balls). This requirement applies only to implantable parts that are exposed to mechanical impact because of their location when implanted.

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

The test protocol to show compliance with this requirement is described in Section 23.2.4.

Manufacturer shall demonstrate compliance to this section.

23.1.5 Immunity of implantable antenna coil to stresses of mechanical flexing and bending

The implantable antenna coil outside the stimulator shall withstand the stress of mechanical flexing and bending that might occur during normal use, manufacturing, or implantation surgery without causing the coil impedance to go out of specification or the failure of functional electrical insulation.

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

The test protocols to show compliance with this requirement are described in Section 23.2.5.

Manufacturer shall demonstrate compliance to this section.

23.1.6 Immunity of implantable leads to tensile forces

Implantable leads outside the stimulator shall withstand the tensile forces that might occur during or after implantation, without failure of any conductor or functional electrical insulation.

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

The test protocols to show compliance with this requirement are described in Section 23.2.6.

Manufacturer shall demonstrate compliance to this section.

NOTE—Annex J contains suggested mechanical tests that might be applicable, dependent upon lead/case design.

23.1.7 Stress relief of junctions in implantable leads

Implantable leads having a junction of two or more conductive components shall be designed so that the junctions are protected from damage caused by the flexural stresses that might occur during or after implantation.

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

The test protocol to show compliance with this requirement is described in Section 23.2.7.

Manufacturer shall demonstrate compliance to this section.

NOTE—These requirements are intended to ensure that adequate studies are carried out to ensure the prevention of fatigue failures of implanted leads.

23.1.8 Immunity of implantable leads to flexural stresses

Implantable leads outside the stimulator shall withstand the flexural stresses that might occur during or after implantation, without failure of any conductor or functional electrical insulation.

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

The test protocols to show compliance with this requirement are described in Section 23.2.8.

Manufacturer shall demonstrate compliance to this section.

23.1.9 Specification of performance of implantable connectors

Implantable connectors, intended for use by physicians to connect implantable parts, shall be identified (see Sections 14.1.2 and 14.2.12). The manufacturer shall declare the intended performance of the connector, as implanted (see Section 8.7), and implantable connectors shall meet the following requirements, if applicable:

a) The quality of connection shall not degrade during use.
b) Reconnection shall be possible without loss of performance of the device.

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

The test protocol to show compliance with this requirement is described in Section 23.2.9.

Manufacturer shall demonstrate compliance to this section.

NOTE—This requirement is in anticipation of future designs; implantable connectors are not used in current system designs.

23.2 Testing for immunity

23.2.1 Testing for immunity to vibration stresses during normal use and handling

This section specifies acceptance testing to show compliance with the requirements for immunity to vibration stresses during normal use and handling, as specified in Section 23.1.1.

The test procedure is as follows: The implantable part of the implant system, mounted in accordance with the requirements and guidance given in IEC 60068-2-47, shall withstand the random vibration test specified in IEC 60068-2-64, Test Fh, under the following conditions:

a) Test frequency range: 5 Hz to 500 Hz
b) Acceleration spectral density: 0.7 $(m/s^2)^2/Hz$
c) Shape of acceleration spectral density curve: flat horizontal, 5 Hz to 500 Hz
d) Duration of testing: 30 min in each of three mutually perpendicular axes

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer‘s design verification test (Section 8.7).

NOTE 1—This vibration test is intended to establish minimum requirements for the durability of the implanted part of an implant system with respect to mechanical robustness.

NOTE 2—The test severity is determined by the test conditions of a) to d). The range of test frequencies is based on experience with the sinusoidal sweep method in common use for a number of years within the pacemaker industry.

23.2.2 Testing for immunity to minor mechanical impact stresses during implantation handling

This section specifies acceptance testing to show compliance with the requirements for immunity to minor mechanical impact stresses during implantation surgery, as specified in Section 23.1.2.

The test procedure is as follows: The implantable part of the implant system shall withstand the mechanical shock test specified in IEC 60068-2-27, Test Ea, under the following conditions:

a) Shock shape: half sine or haversine
b) Severity: peak acceleration: 5,000 m/s^2 (≈510 g-force)
c) Duration of shock: 1 ms
d) Direction and number of shocks: one shock in each direction along three mutually perpendicular axes (for a total of six shocks)

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

23.2.3 Testing for immunity to mechanical impact stresses during normal use, including trauma

This section specifies acceptance testing to show compliance with the requirements for immunity of the implantable component to mechanical impact stresses that might occur during normal use, including trauma, as specified in Section 23.1.3.

The test procedure is as follows:

23.2.3.1 Test 1: Use case impact test applied by hammer to center of implant case

The stimulator of the implant shall be clamped into a testing apparatus and tested in accordance with IEC 60068-2-75, Test Eha or Test Ehc, under the following conditions:

a) Impact energy [J] (± 5 %): 2.5 J
b) Number of impacts: One strike per device per test (protective material + implant)
c) Type of testing apparatus used: pendulum hammer (IEC 60068-2-75, test Eha) or vertical hammer (IEC 60068-2-75, Test Ehc)
d) Striking element: 5-J striking element in accordance with Table 1, IEC 60068-2-75
e) Mounting of the sample undergoing the test: The sample shall be affixed to the rigid supporting surface so that the side facing the cranial bone during normal use (in situ) shall lie evenly on the supporting surface or in a structure representing the shape of the bony bed drilled by the surgeon in the case that the implant's bottom has multiple levels. During impact, a piece of silicone protective material (thickness: 3 mm; size: sufficient to cover the test sample; Shore A hardness: 40° to 60°) shall be placed evenly over the implant between the striking point and the implant. This piece of silicone shall be renewed for each individual test.
f) Pre-treatment: Devices under test shall be pre-soaked in saline at 37 °C for a minimum of one hour.
g) Initial measurements: The device under test shall comply with the requirements of the manufacturer's design verification test (Section 8.7) before it is struck.
h) Position and impact locations: The implant shall be affixed so that the surface, which during normal use (in situ) faces the skin, receives the impact transmitted through the protective material from the hammer strike. The striking element shall hit the specimen (protective material + implant) perpendicularly (i.e., the direction of the striking element's movement shall be normal to the implant's struck surface). The center of the striking element shall hit the protective material at the center of the implant's casing.
i) Securing of base plates, coverings, and similar parts: no special requirements
j) Mode of operation and monitoring of functions: The implant shall not be operating and, therefore, functional monitoring of the implant is not necessary during impact testing.

23.2.3.2 Test 2: Use case impact test applied by hammer to the weakest point or distributed over the device

Test 2 is identical to Test 1 except for the following modification to condition (h) regarding position and impact location: The striking element shall hit the implant's hermetic casing off-centrically at what is considered to be the "weakest" exposed point of the stimulator. The weakest point of the hermetic case can be identified through engineering characterization or finite element analysis. Such points should address connection points for lead wires, minimal internal clearances, the feed-through, or other regions of mechanical vulnerability. The manufacturer shall document the selection of test points.

When the tests are being performed, a restriking (e.g., rebound) shall be avoided.

23.2.3.3 Reporting of test results for Test 1 and Test 2

A test report containing the following information shall be compiled for each test:

a) Denomination of standard and specification
b) Date of test
c) Exact description of the sample
d) Impact test procedure (pendulum hammer or vertical hammer)
e) Exact position of the point of impact (e.g., a drawing)
f) Type of silicone piece used (e.g., product name, source of product, mechanical properties)
g) Exact description of the testing of specifications before and after impact
h) Results of the specification testing
i) Results of the hermeticity test
j) Results of the entire test

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7) and fulfill the hermeticity requirements (gross-leak and fine-leak tests). The allowable moisture limit shall be 5,000 ppm.

23.2.4 Testing for immunity of implantable antenna coil to mechanical impact

This section specifies acceptance testing to show compliance with the requirements for immunity of the implantable antenna coil to mechanical impact stresses that might occur during normal use, including trauma, as specified in Section 23.1.4. This section is not applicable to device designs where the antenna coil is inside the hermetic package.

For the use case impact test applied by hammer to antenna coil, the test procedure is as follows:

The stimulator of the implant system shall be clamped into a testing apparatus and tested in accordance with IEC 60068-2-75, Test Eha or Test Ehc, under the following conditions:

a) Impact energy [J] (± 5 %): 2.5 J.
b) Number of impacts: Up to five strikes per device per test (protective material + implant) at separate locations
c) Type of testing apparatus used: pendulum hammer (IEC 60068-2-75, test Eha) or vertical hammer (IEC 60068-2-75, Test Ehc)
d) Striking element: 5-J striking element in accordance with Table 1, IEC 60068-2-75
e) Mounting of the sample undergoing the test: The sample shall be affixed to a rigid surface whose shape is in accordance with the surgical implant procedure so that the side facing the cranial bone during normal use (in situ) lies evenly on the supporting surface. During impact, a piece of silicone protective material (thickness: 3 mm; size: sufficient to cover the test sample; Shore A hardness: 40° to 60°) shall be placed evenly over the implant between the striking point and the implant. This piece of silicone shall be renewed for each individual strike during this multiple-strike test.
f) Pre-treatment: Devices under test shall be pre-soaked in saline at 37 °C for a minimum of one hour.
g) Initial measurements: The device under test shall comply with the requirements of the manufacturer's design verification test (Section 8.7) before it is struck.
h) Position and impact locations: The antenna coil shall be affixed so that the surface, which during normal use (in situ) faces the skin, receives the impact transmitted through the protective material from the hammer strike. The striking element shall hit the specimen (protective material + implant) perpendicularly (i.e., the direction of the striking element's movement is normal to the implant's struck surface). Single strikes shall be applied at each of five locations on the antenna that are considered vulnerable to mechanical impact. See Figure 18 as an example of the five locations chosen. The manufacturer shall document the selection of the weakest point for impact. The five suggested locations may be reduced based on an engineering analysis. The analysis shall be included in the test report. For example, if the device design is sufficiently symmetrical about a planar axis, the number of unique impact locations may be reduced. Three locations may be chosen and justified per the example in Figure 18, assuming that the antenna coil/device is sufficiently symmetrical about a planar axis at these locations. However, at a minimum, one of these sites shall include the antenna's junction with the case, where flexible wires meet more rigid structures. The following impact locations are also recommended: crossing point of antenna wires and antenna body where silicone over-molding of coil wire is thinnest.
i) Securing of base plates, coverings, and similar parts: no special requirements

j) Mode of operation and monitoring of functions: The implant shall not be operating and, therefore, functional monitoring of the implant is not necessary during impact testing.



Figure 18—Illustration showing the approximate locations for the five strikes for mechanical impact testing of the antenna coil

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7), and none of the following conditions occur, if applicable:

a) The antenna coil magnet is either partially or fully dislodged from its magnet pocket.
b) The electrical resistance or impedance of the antenna coil is higher than the manufacturer's specification.
c) The leakage pathway between the antenna coil and the external saline bath does not meet the manufacturer's specification.

23.2.5 Testing for immunity of implantable antenna coil to stresses of mechanical flexing and bending

This section specifies acceptance testing to show compliance with the requirements for immunity of the implantable antenna coil to mechanical flexion stresses that might occur during normal use, manufacturing, and implantation, as specified in Section 23.1.5. This section only applies to those designs in which the antenna coil design can be flexed or bent into a "U" shape. If a particular design precludes testing, the rationale shall be included in the verification report.

Two modes of antenna coil flexion are tested. Test 1 stresses the antenna coil into an out-of-plane, bowed configuration (commonly referred to as "taco bending"). Test 2 stresses the union of the antenna coil and the stimulator case in a hinged manner along the intersection of the planes of the antenna coil and the stimulator case.

23.2.5.1 Test 1: Antenna coil out-of-plane flex testing

The test procedure is as follows:

1) Select test samples that are in the same condition as devices shipped to the customer.
2) Submerge the test samples in saline for a minimum of 1 hour at room temperature (20 °C [68 °F] to 25 °C [77 °F]) to mimic device temperature during implantation.
3) Subject the test samples to four cycles of being bent into a U-shape by finger-tip application of force to the sides of the antenna until the two sides are vertical (see Figure 19). The inside of the U-shape bend shall be on the top of the antenna (i.e., on the same side as the opening of the magnet pocket). Maintain each bending in the U-shape for 30 sec.
4) Keep the test samples submerged in saline for a minimum of 1 hour at body temperature (37 °C ± 2 °C) to mimic device temperature post-implantation.
5) Commence inspection and performance testing.

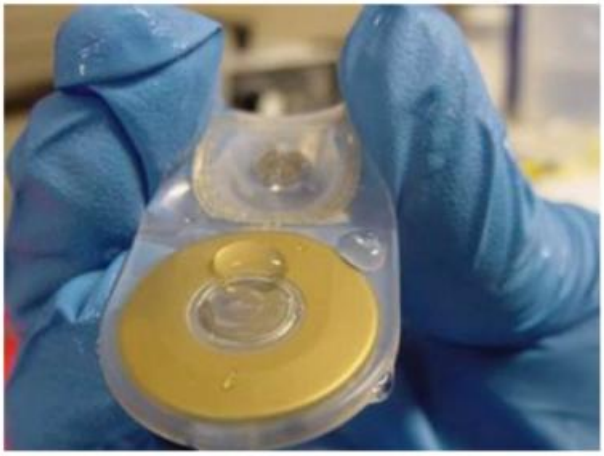


Figure 19—U-shaped flex bending of implantable antenna coil

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7), and none of the following conditions occur, if applicable:

a) The antenna coil magnet is either partially or fully dislodged from its magnet pocket.
b) The electrical impedance of the antenna coil is higher than the manufacturer's specification.
c) A break in the antenna coil is identified by visual inspection under 20x minimum magnification or by X-ray inspection.
d) The leakage pathway between the antenna coil and the external saline bath does not meet the manufacturer's specification.

23.2.5.2 Test 2: Antenna coil hinge flex testing relative to case

The test procedure is as follows:

1) Select test samples that are in the same condition as devices shipped to the customer.
2) Submerge the test samples in saline for a minimum of 1 hour at room temperature (20 °C [68 °F] to 25 °C [77 °F]) to mimic device temperature during implantation.
3) While the test sample remains submerged in the saline, flex the plane of the antenna coil ± 20 degrees relative to the plane of the stimulator case in a hinged manner for 20 cycles in each angular direction. Maintain each bending for 30 sec at the maximum deflection.
4) Keep the test samples submerged in saline for a minimum of 1 hour at body temperature (37 °C ± 2 °C) to mimic device temperature post-implantation.
5) Commence inspection and performance testing.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7), and none of the following conditions occur, if applicable:

a) The antenna coil magnet is either partially or fully dislodged from its magnet pocket.
b) The electrical resistance of the antenna coil is higher than the manufacturer's specification.
c) A break in the antenna coil is identified by visual inspection under 20x minimum magnification or by X-ray inspection.
d) The leakage pathway between the antenna coil and the external saline bath does not meet the manufacturer's specification.

23.2.6 Testing for immunity of implantable leads to tensile forces

This section specifies acceptance testing to show compliance with the requirements for immunity to the stresses of tensile forces applied to the implantable leads, as specified in Section 23.1.6.

Test specimens:

a) Specimen type A shall be an implantable part that is in the same condition as devices shipped to the customer.
b) Specimen type B shall be the implantable lead without the stimulator.

General procedures:

1) Use a saline preconditioning bath of approximately 9 g/l saline at 37 °C ± 5 °C, a tensile load tester, and a voltmeter or an oscilloscope.
2) Keep both specimen types in the preconditioning bath for a minimum of 10 days. Immediately before testing, rinse the test leads in distilled or deionized water, then wipe them free of surface water.
3) Identify that portion of the lead that, when implanted, might be subject to elongation. Devise an appropriate method of clamping the lead to include the elongation portion.

The specific test procedures are provided in Sections 23.2.6.1 and 23.2.6.2.

23.2.6.1 Test 1: Test for specimen type A

The test procedure is as follows:

1) Clamp the specimen type A test sample to the stimulator or the connector, if applicable. Firmly attach another clamp to the most distal part of the lead subject to elongation. Measure the distance between the clamping points.
2) Subject the lead to an elongation of at least 15 mm or a tensile force of minimum 1 Newton, whichever is reached first.
3) Sustain the applied tensile stress for at least one minute, then relieve it.
4) Repeat the tensile load application for each lead.
5) Return the test specimen to the saline bath and immerse it again for a minimum of one hour before proceeding.
6) Verify the electrical continuity of each conduction path (open-circuit test) and insulation (short-circuit test) between each pair of wires inside the lead (if applicable).

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification tests (Section 8.7).

23.2.6.2 Test 2: Insulation test for specimen type B

Specimen type B test samples shall be subjected to the same elongation test as specimen type A samples except that both sides of the lead shall be clamped. Following the elongation test, the insulation shall be subjected to a test voltage. The test signal shall be a 1 kHz square wave with a peak-to-peak voltage of twice the maximum peak-to-peak output voltage of the implant system. The test signal shall be applied between each combination of conducting pairs inside the lead for a minimum of 15 s. The impedance between each pair shall be measured.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification tests (Section 8.7) and the impedance between each pair of conducting wires exceeds 100 kohm.

NOTE—Pediatric patients will experience an increase in skull size of 12 mm (standard deviation of 5 mm) from the round window to the sino-dural angle (Dahm et al., 1993). Leads forming part of an implant system must be designed to withstand the elongation that might be experienced during the skull growth period. If the lead does not allow an elongation of 17 mm, the manufacturer's recommended surgical procedure must avoid extrusion of the electrode array from the cochlea. The specified force of 1 N is considered to be representative of the elongation force acting during bone growth and during implantation. The test method of Section 23.2.6 takes into consideration the differing designs of lead geometry. Although the most appropriate method of lead attachment is left to the manufacturer's discretion, it is required that the critical lead portion subject to elongation by skull growth is identified in the design and subjected to a standard test.

23.2.7 Testing for stress relief of junctions in implantable leads

This section specifies acceptance testing to show compliance with the requirements for stress relief of junctions in implantable leads, as specified in Section 23.1.7.

The method of stress relief testing of junctions in implantable leads is left to the manufacturer's specification.

Compliance is verified by inspection and, if necessary, by review of a design analysis provided by the manufacturer and supported by the manufacturer's calculations and data from test studies, as appropriate.

NOTE—These requirements are intended to ensure that adequate studies are carried out to ensure the prevention of fatigue failures of implanted leads.

23.2.8 Testing for immunity of implantable leads to flexural stresses

This section specifies acceptance testing to show compliance with the requirements for the ability to withstand flexural stresses that might occur during or after implantation, as specified in Section 23.1.8.

23.2.8.1 Test 1: Gross flex testing of leads

The test samples shall be in the same condition as devices shipped to the customer. The tests shall be performed under dry conditions and at room temperature.

The test procedure is as follows:

1) For each sample, affix the lead, with a suitable soft clamping mechanism, in a position 10 mm ± 2 mm proximal from the most proximal electrode contact (see Figure 20).
2) Affix the stimulator so that the center of gravity of the device is at the same height, adjacent to the clamp, and release it five times.

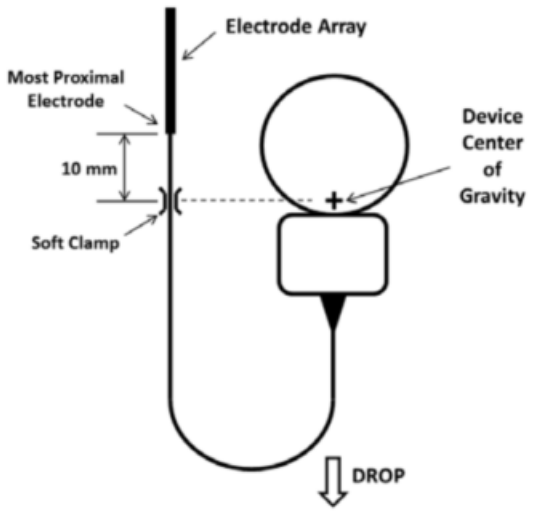


Figure 20—Stimulator drop test

Compliance is verified if the devices under test comply with the requirements of the manufacturer's design verification tests (Section 8.7).

23.2.8.2 Test 2: Cyclical micro flex testing of leads

The test shall be applied to that region of the lead where after implantation flexing can occur because of micro movements. The test samples shall be preconditioned in the same way as the fully assembled and shipped product. The test shall be performed under dry conditions and at room temperature.

A holding fixture made of rigid material shall be used to clamp the stimulator (see Figure 21).

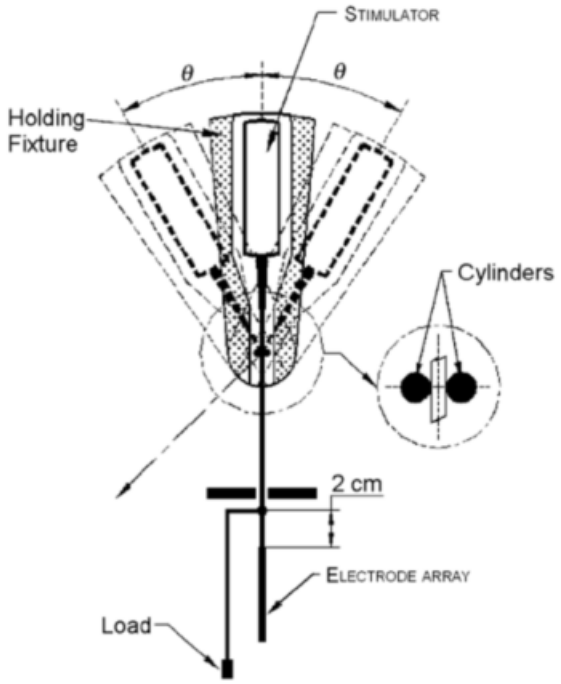


Figure 21—Micro-Flex test fixture

[© ISO. This material is adapted from ISO 14708-1:2014 with permission of the American National Standards Institute (ANSI) on behalf of the International Organization for Standardization. All rights reserved.]

The test procedure is as follows:

1) Mount the holding fixture in an oscillating machine that can flex the lead on either side from the straight direction. The holding fixture shall allow the lead to be tensioned in the direction it exits the stimulator.
2) Feed the lead between two cylinders, both touching the lead. The pivot point shall be in the middle of the line between the centers of both cylinders. The diameter of the cylinders shall be twice the diameter of the lead at the point of the test. If more than one lead exits the stimulator, each lead shall be tested separately.
3) Firmly attach the load to the lead at a point 2 cm ± 0.2 cm from the most proximal electrode. The total load shall apply 0.03 N ± 0.01 N.
4) Oscillate the holding fixture at least 15 degrees on each side at a rate of approximately 2 Hz for a minimum of 100,000 cycles.

Alternatively, an equivalent test may be performed in which the stimulator remains stationary and the lead is oscillated, provided that all other test conditions remain the same.

Compliance is verified if the devices under test comply with the requirements of the manufacturer's design verification tests (Section 8.7).

NOTE—When drafting this standard, the committee observed that recommended clinical practice is to implant the implantable part of an implant system within a bony bed. This approach provides maximum stability to the implanted

part and its associated electrode array and is considered state of the art. Tests 1 and 2 are intended to establish minimum requirements for the flexural durability of implantable leads. Test 1 is designed to simulate any adverse handling conditions that might be experienced during removal of the device from the sterile barrier system and handling it prior to implantation. Test 2 acknowledges that variation in implantation technique might exist and is designed to simulate micro movement of the lead after implantation, especially in the region of the temporalis muscle. However, it is also acknowledged that if the recommended implantation technique is used, micro movement of the lead can be significantly reduced.

Although the exact conditions are impossible to determine, it is believed that shearing and bending causes similar stress conditions to those experienced in *in vivo* failures. A 3 g weight is attached to the test segment to force the test sample to conform to the required angular displacement without providing a significant tensile load. Bending the test sample by 15 degrees for 100 000 cycles creates a more severe strain at the electrode than is expected *in vivo*.

23.2.9 Testing of implantable connectors

This section specifies acceptance testing to show compliance with the requirements for performance of implantable connectors, as specified in Section 23.1.9.

NOTE—The method of providing a secure connection is left to the manufacturer‘s specification. Thus, the manufacturer is required to specify compatible connector parts (see Sections 12.3 and 14.2.12) so that specified parts can be selected for test, ensuring that implanted connector pairs are reliable when subject to tensile force.

24 Device immunity to stresses caused by atmospheric pressure changes

24.1 Minimum operating range

A minimum operational range for atmospheric pressure shall be defined for implantable components:

a) A lower pressure limit of 70 kPa, corresponding to an altitude of approximately 3000 m (i.e., 30 kPa below normal atmospheric pressure, where 1 atm = 101 kPa)
b) An upper pressure limit of 150 kPa, corresponding approximately to a depth of 5 m in water (i.e., 50 kPa above normal atmospheric pressure)

Manufacturer shall demonstrate compliance to this section.

24.2 Requirements for immunity

24.2.1 Immunity to pressure changes during transit or normal use

Implantable parts of a cochlear implant system shall be constructed to withstand the changes of atmospheric pressure that might occur during transit or normal conditions of use.

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

The test protocol to show compliance with this requirement is described in Section 24.3.1.

Manufacturer shall demonstrate compliance to this section.

24.2.2 Immunity to increases in atmospheric pressure during vocational or recreational activities

Implantable parts of an implant system shall be constructed to withstand foreseeable increases in pressure that might occur during vocational or recreational activities.

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

The test protocol to show compliance with this requirement is described in Section 24.3.2.

Labeling shall include specification in the product data sheet (Section 12.1) of the operational pressure limits of the device during vocational or recreational use, expressed in both metric and English units as both absolute atmospheric pressure and the equivalent altitude or depth relative to sea level.

Manufacturer shall demonstrate compliance to this section.

24.3 Testing for immunity

24.3.1 Testing for immunity to pressure changes during transit or normal use

Testing shall be conducted using four atmospheric pressure test protocols, including static and cyclic testing at the limits of the minimal operational range (see Sections 24.3.1.1 through 24.3.1.4).

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

24.3.1.1 Test for static low atmospheric pressure

The device shall be placed in a suitable test fixture and cycled one time from ambient pressure to a pressure of 70 kPa ± 3.5 kPa (± 5 %) or lower, then back to ambient pressure. The rate of pressure change shall be at least 100 kPa per minute. The minimum pressure shall be maintained for at least one hour. Testing shall be performed at 22 °C ± 5 °C.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

24.3.1.2 Test for cyclic low atmospheric pressure

The device shall be placed in a suitable test fixture and cycled 20 times from ambient pressure to a pressure of 70 kPa ± 3.5 kPa (± 5 %) or lower, then back to ambient pressure. The rate of pressure change shall be at least 100 kPa per minute. The minimum and ambient pressures shall each be maintained for at least one minute per cycle. Testing shall be performed at 22 °C ± 5 °C.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

24.3.1.3 Test for static high atmospheric pressure

The device shall be placed in a suitable test fixture and cycled one time from ambient pressure to a pressure of at least 150 kPa ± 7.5 kPa (± 5 %), then back to ambient pressure. The rate of pressure change shall be at least 100 kPa per minute. The maximum pressure shall be maintained for at least one hour. Testing shall be performed at 22 °C ± 5 °C.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test(Section 8.7).

24.3.1.4 Test for cyclic high atmospheric pressure

The device shall be placed in a suitable test fixture and cycled 20 times from ambient pressure to a pressure of at least 150 kPa ± 7.5 kPa (± 5 %), then back to ambient pressure. The rate of pressure change shall be at least 100 kPa per minute. The maximum and ambient pressures shall each be maintained for at least one minute per cycle. Testing shall be performed at 22°C ± 5°C.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

24.3.2 Testing for immunity to increases in atmospheric pressure during vocational or recreational activities

The device shall be placed in a suitable saline-filled pressure chamber and cycled 20 times from ambient pressure to a maximum pressure and back to ambient pressure. The maximum test pressure shall be 1.5 times the highest operational pressure specified in the manufacturer's documentation (see Sections 12.1 and 12.10). The rate of pressure change shall be at least 100 kPa per minute. The maximum and ambient pressures shall each be maintained for at least one minute per cycle. Testing shall be performed at 22 °C ± 5 °C.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

NOTE—This test simulates in part the increased pressure that might occur during particular occupational or recreational activities, such as scuba diving. This test was included in response to increased user expectations.

25 Device immunity to stresses caused by temperature changes

25.1 Requirements for immunity to temperature extremes in transport and storage

Implantable parts of a cochlear implant system shall be designed and constructed so that no irreversible damage will be caused by the changes in temperature to which they might be subjected during transport and storage.

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

The test protocol to show compliance with this requirement is specified in Section 25.2. Compliance is verified by inspection of test results and labeling, as applicable.

Manufacturer shall demonstrate compliance to this section.

25.2 Testing for immunity to temperature extremes in transport and storage

Manufacturers shall conduct tests to verify that a sample of parts meets or exceeds the minimum requirements established by the tests for the durability of the part. The tests are specified in the following subsections.

25.2.1 Test for low-temperature storage

This test is based on IEC 60068-2-1, Test Ab ("Cold for non-heat-dissipating specimen with gradual change of temperature") and is intended to detect irreversible damage to the test sample from exposure to sustained low temperatures that might occur during storage.

The test shall be conducted with the device in the sterile barrier system. Beginning at ambient room temperature, the device temperature shall be lowered at a rate of <1 °C/min (averaged over 5 min) to the lowest storage value specified by the manufacturer or –10 °C ± 3 °C (whichever is more severe). This minimum temperature shall be maintained for 16 hours, at which point the device is returned to ambient temperature at a corresponding rate.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

NOTE—It is known that some implants cannot withstand freezing. This issue should be addressed in the relevant particular standard (part of ISO 14708). For any device that cannot be withstand the full temperature range specified by this subsection, additional warning notices on the packaging will be required (see Section 14.2.13). If damage caused by freezing is not immediately apparent, then special temperature indicators might be required in the packaging.

25.2.2 Test for dry-heat storage

This test is based on IEC 60068-2-2, Test Bb ("Dry heat for non-heat-dissipating specimen with gradual change of temperature") and is intended to detect irreversible damage to the test sample from exposure to sustained high temperatures that might occur during storage.

The test shall be conducted with the device in the sterile barrier system. Beginning at ambient room temperature, the device temperature shall be raised at a rate of <1 °C/min (averaged over 5 min) to the highest storage value specified by the manufacturer or 55 °C ± 2 °C (whichever is more severe). This maximum temperature shall be maintained for 16 hours, at which point the device is returned to ambient temperature at a corresponding rate.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

NOTE—If the device under test contains temperature-sensitive components, adjust the lower and/or upper temperature limits for storage, transport, and normal use accordingly. Provide a justification for the changed test limit(s). Ensure that the product labeling reflects any such changes.

25.2.3 Test for thermal cycling during storage and transport

This test is based on IEC 60068-2-14, Test Nb ("Change of temperature with specified rate of change") and is intended to test for irreversible damage to the test sample from exposure to thermal cycling during storage and transport.

The test shall be conducted with the device in the sterile barrier system. Beginning at ambient room temperature, the device temperature shall be raised at a rate of <1 °C/min (averaged over 5 min) to the highest storage value stated by the manufacturer or 55 °C ± 2 °C (whichever is more severe). This maximum temperature shall be maintained for 3 hours, at which point the device temperature is lowered to the lowest storage value specified by the manufacturer or –10 °C ± 3 °C (whichever is more severe) at a corresponding rate. The minimum temperature shall be maintained for 3 hours before the cycle is repeated. At the end of the second cycle, the device is returned to ambient temperature at the corresponding rate.

Acceptable performance is verified if the devices under test comply with the requirements of the manufacturer's design verification test (Section 8.7).

NOTE 1—If the device under test contains temperature-sensitive components, adjust the lower and/or upper temperature limits for storage, transport, and normal use accordingly. Provide a justification for the changed test limit(s). Ensure that the product labeling reflects any such changes.

NOTE 2—It is known that some implants cannot withstand freezing. This issue should be addressed in the relevant particular standard (part of ISO 14708). For any device that cannot be withstand the full temperature range specified by this subsection, additional warning notices on the packaging will be required (see Section 14.2.13). If damage caused by freezing is not immediately apparent, then special temperature indicators might be required in the packaging.

26 Non-implantable device immunity to stresses caused by environment and usage

NOTE—The requirements for non-implantable components to withstand the external stresses of environment and usage are organized into three parts, depending on the degree and type of stress and on the relative permanence of various non-implantable components.

The configuration of the samples shall be in line with the test objective. Transportation tests are performed on samples that are in their packaging. Usage tests are performed on samples in the expected use configuration, generally without any packaging.

26.1 Requirements for immunity of sound processor and body-worn accessories

Sound processors and body-worn accessories shall be constructed to withstand environmental stresses that might occur during conditions of normal use, transport, and storage. These stresses include changes in temperature, relative humidity, atmospheric pressure, mechanical forces (e.g., vibration and shock), and ingress of foreign objects and water.

Headpiece coils are considered an integral part of the sound processor and are covered in this requirement.

The durability of body-worn sound processors and their susceptibility to external stresses are significant factors in the daily lives of cochlear implant recipients. Consequently, the reliability of these components is examined and reported according to the requirements of Section 11.

Body-worn accessories are ancillary devices that might be used with sound processors to extend the processors' basic operation or body-worn configuration. Examples are battery packs, FM systems that connect to the sound processors, and accessory microphones.

Additional requirements for body-worn parts are contained in Section 16.2 (headpieces) and Section 19 (battery packs).

Manufacturers shall conduct tests to verify that a sample of parts meets or exceeds the minimum requirements for the durability of the part. The specific immunity requirements are detailed in the following subsections.

Acceptable performance is verified if the components under test comply with the requirements of the manufacturer's design verification test (Section 8.7). Compliance is verified by inspection of test results.

Manufacturer shall demonstrate compliance to this section.

26.1.1 Temperature

Sound processors, headpieces, and remote controls shall be constructed to withstand the changes of temperature that might occur during transit, storage, and normal conditions of use.

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

26.1.2 Relative humidity

Sound processors, headpieces, and remote controls shall be constructed to withstand the changes of relative humidity that might occur during transit, storage, and normal conditions of use.

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

26.1.3 Atmospheric pressure

Sound processors, headpieces, and remote controls shall be constructed to withstand the changes of atmospheric pressure that might occur during transit, storage, and normal conditions of use.

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

26.1.4 Mechanical forces

Sound processors, headpieces, and remote controls shall be constructed to withstand the mechanical forces that might occur during transit, storage, and normal conditions of use.

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

26.1.5 Moisture ingress

Sound processors, headpieces, and remote controls shall be constructed to withstand the moisture ingress that might occur during transit, storage, and normal conditions of use.

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

26.2 Testing for immunity of sound processors and body-worn accessories

The individual tests specified here are based on applicable test standards that require the part under test to be subjected to a range of environmental stresses according to a prescribed test protocol. After the test protocol is completed, the tested device undergoes the following:

a) Visual examination to detect any mechanical damage
b) Electrical and mechanical functional tests

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

Acceptable performance is verified if the components under test comply with the requirements of the manufacturer's design verification test (Section 8.7). Compliance is verified by inspection of test results.

26.2.1 Temperature

Manufacturers shall conduct on each of the test samples four different tests, which simulate temperature conditions of transport, storage, and normal use. Manufacturers can choose between the test methods described in the subsections below and those specified in IEC 60601-1-11.

26.2.1.1 Test for low-temperature storage

This test is based on IEC 60068-2-1, Test Ab ("Cold for non-heat-dissipating specimen with gradual change of temperature") and is intended to test for irreversible damage to the test sample from exposure to sustained low temperatures that might occur during storage.

Beginning at ambient room temperature, the device temperature shall be lowered at a rate of <1 °C/min (averaged over 5 min) to –40 °C ± 3 °C. This minimum temperature shall be maintained for 16 hours, at which point the device is returned to ambient temperature at a corresponding rate.

26.2.1.2 Test for dry-heat storage

This test is based on IEC 60068-2-2, Test Bb ("Dry heat for non-heat-dissipating specimen with gradual change of temperature") and is intended to test for irreversible damage to the test sample from exposure to sustained high temperatures that might occur during storage.

Beginning at ambient room temperature, the device temperature shall be raised at a rate of <1 °C/min (averaged over 5 min) to 70 °C ± 2 °C. This maximum temperature shall be maintained for 16 hours, at which point the device is returned to ambient temperature at a corresponding rate.

NOTE—If the device under test contains liquid-crystal displays (LCDs), batteries, microphones, or other temperature-sensitive components, adjust the lower and/or upper temperature limits for storage, transport, and normal use accordingly. Provide a justification for the changed test limit(s), which should be reflected in the product labeling.

26.2.1.3 Test for thermal cycling during normal use

This test is based on IEC 60068-2-14, Test Nb ("Change of temperature with specified rate of change") and is intended to test for irreversible damage to the test sample from exposure to thermal cycling during normal use. The range of thermal cycling shall span the minimum and maximum operating temperatures per the manufacturer's labeling specification for normal use.

Beginning at ambient room temperature, the device temperature shall be raised at a rate of <1 °C/min (averaged over 5 min) to the maximum temperature. This maximum temperature shall be maintained for 3 hours, at which point the device temperature is lowered to the minimum temperature at a corresponding rate. The minimum temperature shall be maintained for 3 hours before the cycle is repeated. At the end of the second cycle, the device is returned to ambient temperature at the corresponding rate.

NOTE 1—It is expected that some parametric measurements will be outside of tolerance, which is acceptable, provided that the devices remain functional. Parametric measurements should be repeated after the device returns to standard room conditions to ensure that the device is within specification. The functionality of every device under test should be checked at each extreme value of the test range, before and after the thermal cycling test. (For example, if a sound processor with coil and shipping program map is switched on and functions correctly, no error notification should occur.)

NOTE 2—If the device under test contains LCDs, batteries, microphones, or other temperature-sensitive components, adjust the lower and/or upper temperature limits for storage, transport, and normal use accordingly. Provide a justification for the changed test limit(s), which should be reflected in the product labeling.

26.2.1.4 Test for thermal cycling during storage and transport

This test is based on IEC 60068-2-14, Test Nb ("Change of temperature with specified rate of change") and is intended to test for irreversible damage to the test sample from exposure to thermal cycling during storage and transport.

Beginning at ambient room temperature, the device temperature shall be raised at a rate of <1 °C/min (averaged over 5 min) to 70 °C ± 2 °C. This maximum temperature shall be maintained for 3 hours, at which point the device temperature is lowered to –40 °C ± 3 °C at a corresponding rate. The minimum temperature shall be maintained for 3 hours before the cycle is repeated. At the end of the second cycle, the device is returned to ambient temperature at the corresponding rate.

NOTE—If the device under test contains LCDs, batteries, microphones, or other temperature-sensitive components, adjust the lower and/or upper temperature limits for storage, transport, and normal use accordingly. Provide a justification for the changed test limit(s), which should be reflected in the product labeling.

26.2.2 Relative humidity

Manufacturers shall conduct on each of the test samples a cyclic damp-heat test that simulates the relative humidity conditions of transport, storage, and normal use. This test should be performed in accordance with either IEC 60601-1-11 or IEC 60068-2-30, Test Db ("Damp heat, cyclic, 12 + 12 hour cycle"). Variant 1 shall be used because of the hollow spaces and breathing effects in sound processors.

26.2.3 Atmospheric pressure

Manufacturers shall conduct on each of the test samples the following test, which simulates the atmospheric pressure conditions during transport, storage, and normal use. Manufacturers can choose either the test method described in the Section 26.2.3.1 or those specified in IEC 60601-1-11.

NOTE 1— It is expected that some parametric measurements will be outside of tolerance, which is acceptable, provided that the devices remain functional. Parametric measurements should be repeated once the device returns to standard room conditions to ensure that the device remains in specification.

26.2.3.1 Test for static low atmospheric pressure

The device shall be placed in a suitable test fixture and cycled one time from ambient pressure to a minimum pressure of 50 kPa ± 2.5 kPa (± 5 %), then back to ambient pressure. The rate of pressure change shall be at least 100 kPa per minute. The minimum pressure shall be maintained for at least one hour. Testing shall be performed at 22 °C ± 5 °C.

26.2.4 Mechanical forces

Manufacturers shall conduct on each of the test samples four different tests, which simulate the mechanical stress conditions of transport, storage, and normal use. Manufacturers can choose either the test methods described in the subsections below or those specified in IEC 60601-1-11.

NOTE 1—This section of the standard specifies mechanical stress tests for hand-held, portable parts and body-worn components of active implantable medical devices. As applied to sound processors, it tests the mechanical robustness of the device and removes the need for a separate, less stringent shock test (for which there is no regulatory requirement). A 2 m drop height for behind-the-ear (BTE) and head-worn equipment is a mandatory regulatory requirement as the worst case of normal use, more severe than the 1.5 m minimum standard requirement. A 1 m drop height is relevant to testing remote controls and child-worn equipment.

NOTE 2—The vibration test below specifies a frequency range of 5 Hz to 150 Hz. If it is impractical to test to the 5 Hz limit because of test equipment limitations, a frequency range of 10 Hz to 150 Hz is acceptable.

NOTE 3—A failure point can be identified by conducting visual inspection after each drop from heights of 1 m and/or 2 m and conducting functional unit checks after each 10 drops. (This is guidance for data collection; this standard does not require that tests be conducted after each drop.) Pass results from any test conducted after fewer than the specified number of drops do not constitute any portion of a pass for this test.

26.2.4.1 Test for vibration

This test is based on IEC 60068-2-64, Test Fh ("Vibration, broadband random and guidance") and is intended to test for irreversible damage to the test sample from exposure to sustained, broadband random vibrations that might occur during transport.

The test shall be conducted over a frequency range of either 5 Hz to 150 Hz or 10 Hz to 500 Hz. The acceleration spectral density (ASD) shall be 0.1 g^2/Hz. The vibration shall be applied for 30 min along each of three mutually orthogonal axes, which the manufacturer shall describe.

26.2.4.2 Test for free-fall shock (1 m; in-use orientation)

This test is based on IEC 60068-2-31, Test Ec ("Rough handling shocks, primarily for equipment-type specimens") and is intended to test for irreversible damage to the test sample from exposure to mechanical shock sustained in a free-fall event.

The test surface shall be hard wood having a density of ≥ 630 kg/m^3 and a thickness of 50 mm to 55 mm. The drop height shall be 1 m above the test surface. The drop orientation shall be "in-use" and shall be described by the manufacturer. Each tested device shall be dropped twice.

26.2.4.3 Test for free-fall shock (2 m; in-use/side-on orientation)

This test is based on IEC 60068-2-31, Test Ec ("Rough handling shocks, primarily for equipment-type specimens") and is intended to test for irreversible damage to the test sample from exposure to mechanical shock sustained in a free-fall event.

The test surface shall be hard wood having a density of ≥ 630 kg/m^3 and a thickness of 50 mm to 55 mm. The drop height shall be 2 m above the test surface. The drop orientations shall be "in-use" and "side on" and shall be described by the manufacturer. Each tested device shall be dropped twice in each drop orientation. "Side on" orientation shall include any surface that has a user control or connector.

26.2.4.4 Test for free-fall shock (1 m; random orientation)

This test is based on IEC 60068-2-31, Test Ec ("Rough handling shocks, primarily for equipment-type specimens") and is intended to test for irreversible damage to the test sample from exposure to mechanical shock sustained in a free-fall event.

The test surface shall be hard wood having a density of ≥ 630 kg/m^3 and a thickness of 50 mm to 55 mm. The drop height shall be 1 m above the test surface. The drop orientations shall be uncontrolled free-fall events. Each tested device shall be dropped twice during the test.

26.2.5 Moisture ingress

The test for moisture ingress shall be conducted in accordance with the degree of protection chosen by the manufacturer per IEC 60529, *Degrees of protection provided by enclosures (IP code)*.

The use conditions shall be defined by the following:

a) How often per year the user is expected to subject the device to moisture

   NOTE—Multiply this number by the number of years of device life to determine the number of moisture exposure cycles to which the devices under test must be subjected.

b) The types of water to be specified in the labeling claim (e.g., bath water, soapy water, salt water)

c) The level of moisture protection to be claimed for the device per IEC 60529. The level of protection specified by the manufacturer must be in accordance with the intended claim. For example, a claim of IPx4 for splash-proof could not be used to support a claim that a device is for swimming or bathing.

See IEC 60529 for the allowable levels and test method.

The test conditions need to be specified only for the IPx8 rating. For all other IP ratings, IEC 60529 test conditions can be used. If the manufacturer selects an IPx8 rating for the water protection claim, the following test conditions shall be specified:

a) Depth of submersion
b) Length of submersion
c) Number of exposures, as defined above

Test methods shall include all water use cases and claims

For IPx8 ratings, testing shall be conducted in accordance with the following procedure:

1) Place the device under test into water of the type specified at the depth specified and under the use conditions specified.

   NOTE—The water depth can be the actual depth specified or simulated under pressure.

2) Leave the device in the water for the specified length of time.
3) Repeat steps 1) and 2) for the required number of cycles.
4) Perform the manufacturer's functional testing to verify both the device performance claim and the use claim.
5) Repeat all steps for each type of water specified in the labeling.

26.3 Testing for immunity of cables

At minimum, cable testing shall include the tests listed in Table 9. The requirements in this section apply to all cables necessary for stand-alone operation in all wearing configurations.

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

Acceptable performance is verified if the components under test comply with the requirements of the manufacturer's design verification test (Section 8.7). Compliance is verified by inspection of test results.

Manufacturer shall demonstrate compliance to this section.

Table 9—Summary of functional tests for cables

Test	Section	Equipment
Tug test	26.3.1	Pull tester
Multiple-pin plug cyclic connection test	26.3.2	N/A (by hand)
Bite test	26.3.3	Force gauge, artificial teeth
Pull test	26.3.4	Pull tester
Flex test	26.3.5	Flex tester

26.3.1 Tug test

The use conditions shall be defined by the following:

a) How many times per day and per year a user is expected to tug on the cable
b) The expected tug force specified by the manufacturer

The test setup is shown in Figure 22. The purpose of this test is to verify the cable conductor integrity.

The test procedure is as follows:

1) Check for open circuits by connecting the wires in the device under test to the digital multimeters (DMMs).
2) Secure the device under test to the pull tester at each end, using securing blocks, clamps, or vices.
3) Begin the test.
4) Raise the top clamp, at the specified pull rate, until the specified pull force is reached; then relax the clamp.
5) Repeat step 4) until the device fails the continuity test or until the number of cycles equivalent to at least the required years of use (as specified by the manufacturer) has been reached.
6) Record the number of cycles after which continuity ceased.

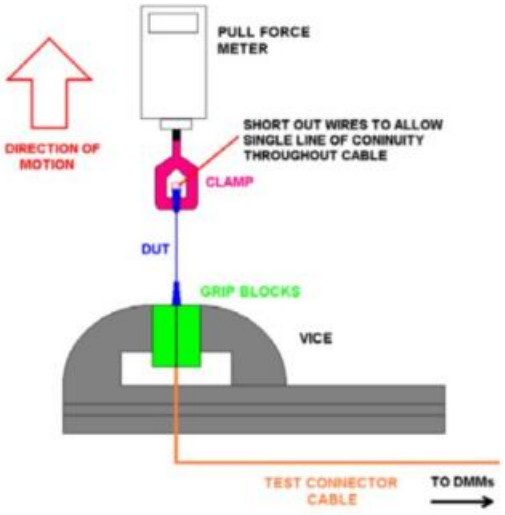


Figure 22—Test setup for cable tug test

The test pull force is the expected tug force or the maximum connector disengage force, whichever is greater.

26.3.2 Test for multiple-pin plug cyclic connection

The use conditions shall be defined by how many times per day and per year the user is expected to connect and disconnect the cable.

The test setup is shown in Figure 23.

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

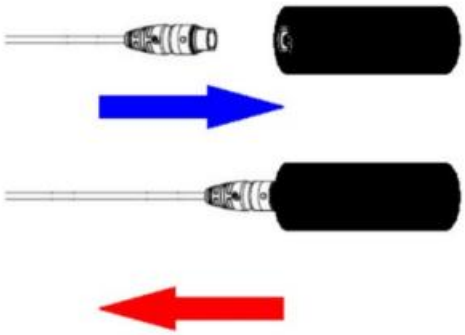


Figure 23—Test setup for 6-pin plug cyclic connection test

The test procedure is as follows:

1) Fully connect the plug to the socket manually.
2) Fully remove the plug from the socket manually.
3) Repeat the connect/disconnect cycle for the number of cycles equivalent to a maximum of 6 months of use.
4) Functionally test the cable (Section 8.7).
5) Repeat steps 1) through 4) until either the equivalent of the required years (as specified by the manufacturer) of use is completed or all devices under test have failed the functionality testing of Section 8.7.
6) If applicable, record the number of cycles after which the continuity fails.

26.3.3 Bite test

The test procedure is as follows:

1) Using a bite test clamp (Figure 24) or an equivalent test jig (Figure L1, Appendix L, AS 1647.2-1992), place the device under test between the upper and lower jaws.
2) Apply a compressive force of 140 N ± 2.5 N on the clamping site for a period of 5 seconds.
3) Maintain the force of 140 N ± 2.5 N (the specified force) for an additional 10 seconds.
4) Remove the force and remove the device under test from the test clamp or teeth.
5) Inspect the clamped area for signs of damage and sharp edges.

Acceptable performance is verified if the devices under test do not have any sharp points or edges, and if no parts are severed. The intent of this test is not to verify electrical safety or functionality.

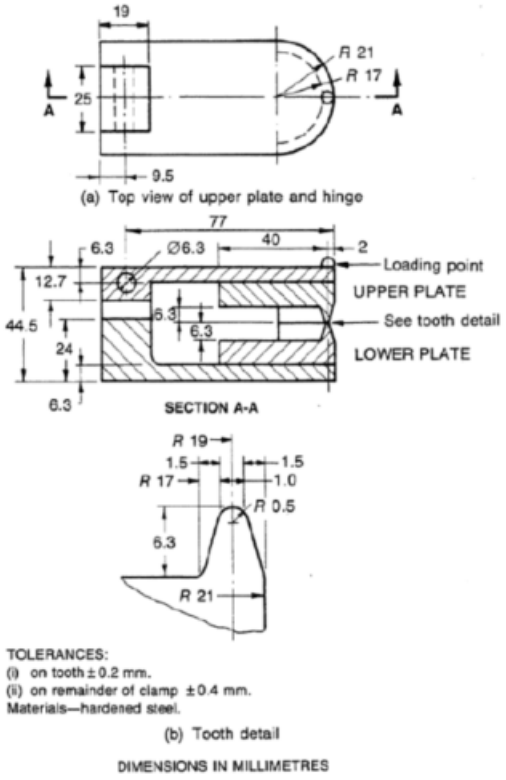


Figure 24—Fixture for bite test

[Reprinted from AS 1647.2-1992 Figure L1 © Standards Australia Limited with the permission of Standards Australia under Licence 1702-c080]

26.3.4 Pull test

Figure 25 shows the test setup.

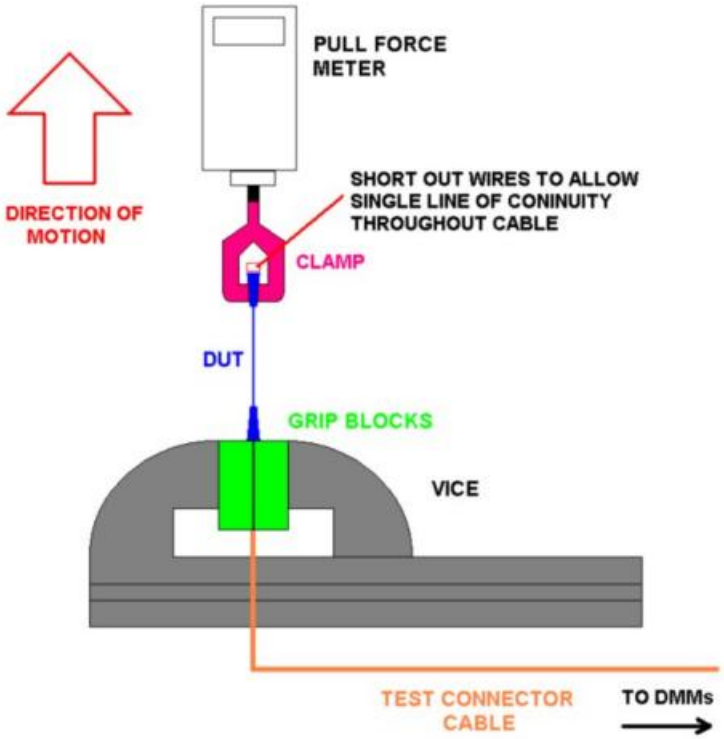


Figure 25—Test setup for cable pull test

The test procedure is as follows:

a) Short the wires at one end to allow continuity to be checked from one end.
b) Connect the device under test to the DMM(s).
c) Secure the device under test to the pull tester, using securing blocks, clamps, or vices.
d) Begin the test.
e) Raise the top clamp at a specified rate until continuity is lost, according to the functionality test specified in Section 8.7.
f) Analyze the results to determine the average strength of the cables.

The strength of each cable and the average strength of the entire set of samples shall exceed the required force.

NOTE— A 70 N pull force is recommended.

26.3.5 Flex test

The test procedure is as follows:

1) The manufacturer shall specify the flex test conditions expected during use.
2) Perform functional testing according to Section 8.7.
3) Connect the device under test to the flex test monitoring setup.
4) Place one end in holding blocks at the defined position from the end of the cable strain relief.
5) Mount holding blocks into the flex tester.
6) Begin flex testing and monitor for wire breakages.
7) Test for the equivalent of a maximum of 6 months of simulated life.
8) Perform functional testing according to Section 8.7.

9) Repeat Steps 5) to 7) until the equivalent of the required years of simulated use (as specified by the manufacturer) has been completed.
10) Repeat Steps 3) to 8) using the other end of the cable.

Compliance with the acceptance criteria is based on the combined result of the flex results for both ends.

26.3.6 Connector engage and retention force

The manufacturer shall develop device specifications and test acceptance criteria taking into consideration human factors and typical use. The specifications shall include the force (N) necessary to engage and disengage the cable connector for a new cable and for a cable at end of life. Tests shall be conducted both in-line and at right angles to the connector axis.

26.3.7 Cable safety

Manufacturers shall consider the potential harm that can result from the use of cables. Manufacturers shall describe these hazards and the associated mitigations in the product risk management file. The manufacturer shall include in the product labeling a warning concerning the specific risks of cables when used with infants and young children (see Section 12.18).

NOTE—An example is the choking hazard that can result from a long cable, particularly for infants. A mitigation against choking might be to keep the cable length to less than 220 mm with a pull force of 25 ± 2 N, as recommended in AS/NZS ISO 8124.1:2002.

26.4 Requirements for immunity of non-body-worn accessories

Non-body-worn accessories (e.g., programming interfaces, audiological equipment, diagnostic equipment, supporting cables, specialized hardware for hybrid applications, battery chargers, or other components that the manufacturer might provide for support of the cochlear implant system) shall be constructed to withstand environmental stresses that might occur during conditions of normal use, transport, and storage. These stresses include changes in temperature, relative humidity, atmospheric pressure, mechanical forces (e.g., vibration and shock), and ingress of foreign objects and water.

Manufacturers shall conduct tests to verify that a sample of parts meets or exceeds the minimum requirements established by the tests for the durability of the part. The specific tests are specified in the following subsections.

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

Acceptable performance is verified if the components under test comply with the requirements of the manufacturer’s design verification test (Section 8.7). Compliance is verified by inspection of test results.

Manufacturer shall demonstrate compliance to this section.

26.4.1 Temperature

Non-body-worn accessories shall be constructed to withstand the changes in temperature that might occur during transit, storage, and normal conditions of use.

26.4.2 Relative humidity

Non-body-worn accessories shall be constructed to withstand the changes in relative humidity that might occur during transit, storage, and normal conditions of use.

26.4.3 Atmospheric pressure

Non-body-worn accessories shall be constructed to withstand the changes in atmospheric pressure that might occur during transit, storage, and normal conditions of use.

26.4.4 Mechanical forces

Non-body-worn accessories shall be constructed to withstand the mechanical forces that might occur during transit, storage, and normal conditions of use.

26.5 Testing for immunity of non-body-worn accessories

26.5.1 Temperature

Manufacturers shall conduct on each of the test samples four different tests that simulate the temperature conditions of transport, storage, and normal use. Manufacturers can choose either the test methods described in the subsections below or those specified in IEC 60601-1-11.

26.5.1.1 Test for low-temperature storage

See the test specified in Section 26.2.1.1 for sound processors and body-worn accessories.

26.5.1.2 Test for dry-heat storage

See the test specified in Section 26.2.1.2 for sound processors and body-worn accessories. The maximum test temperature shall be 50 °C ± 2 °C.

26.5.1.3 Test for thermal cycling during normal use

See the test specified in Section 26.2.1.3 for sound processors and body-worn accessories. The test temperature range shall be +5 °C to +40 °C.

26.5.1.4 Test for thermal cycling during storage and transport

See the test specified in Section 26.2.1.4 for sound processors and body-worn accessories.

26.5.2 Relative humidity

See the test specified in Section 26.2.2 for sound processors and body-worn accessories.

The functionality of each device under test shall be checked at the extreme values of the design range for normal operation design (10 % to 95 % RH), before and after the humidity cycling test. A programming interface should enable successful communication between a personal computer and a sound processor.

26.5.3 Atmospheric pressure

See the tests specified in Section 26.2.3 for sound processors and body-worn accessories.

The functionality of each device under test shall be checked for normal operation, before and after the pressure cycling test. A programming interface should enable successful communication between a PC and a sound processor.

26.5.4 Mechanical forces

Manufacturers shall conduct on each of the test samples two different tests that simulate the mechanical stress conditions of transport, storage, and normal use. Manufacturers can choose either the test methods described in the subsections below or those specified in IEC 60601-1-11.

26.5.4.1 Test for vibration

See the test specified in Section 26.2.4.1 for sound processors and body-worn accessories.

26.5.4.2 Test for free fall (1 m for handheld components)

See the test specified in Section 26.2.4.2 for sound processors and body-worn accessories. The drop height shall be 1 m.

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Annex A
(informative)

Clinical identification and management of cochlear implant device failures

It is the responsibility of the cochlear implant (CI) surgeon and audiologist to monitor the function of the CI system and to make decisions regarding device explantation and reimplantation when failure of the internal device is suspected or confirmed. Failure to diagnose a problem with the internal device can have severe, long-term ramifications for patient outcomes. Thus, clinical management of patients with cochlear implants includes regular evaluation of internal and external components, coupled with regular evaluations of patient performance, to determine if a device is functioning properly.

Cochlear implant internal device failures can be straightforward (e.g., hard failures that result in a complete loss of sound) or complex (e.g., device failures that are determined to be "out of specification" by both clinical testing and reduced clinical benefit). Documentation of device analysis and evaluation of patient performance is necessary because it is often difficult to determine the source of poor or reduced performance. Explantation and reimplantation should be considered if it is believed that the benefits of the procedure outweigh the risks.

Several measures should be taken during the implant process to identify a possible device failure:

- *Preoperative measures*
  - Patients and/or family members should receive counseling regarding the possibility of device failure, including information about device reliability.
  - Clinicians should obtain a detailed case history, conduct a medical evaluation, and perform preoperative testing to derive an estimate of the anticipated outcome with a cochlear implant; not all patients will do well with a CI so it is important to be aware of factors that could contribute to poor outcomes.
  - Poorer performance with a CI (as compared to preoperatively with a hearing aid) is not expected and could be indicative of CI device failure. Thus, it is important to perform adequate speech recognition testing with appropriate amplification as part of the preoperative evaluation process.
  - In cases of structural abnormalities, radiographic testing and preoperative objective measurements (e.g., electrical auditory brainstem response [EABR]) can be used to develop the prognosis for stimulability of the selected ear.

- *Intraoperative measures*
  - Intraoperative objective measurements may be taken through the implant to verify the gross function of the device (e.g., impedance telemetry, evoked compound action potential [eCAP], electrical stapedial reflex threshold [eSRT], EABR) before device activation and can serve as a baseline for future comparison if concerns about performance arise.
  - A transorbital x-ray may be obtained immediately following implantation or at the time of device activation to verify electrode placement and/or to alert clinicians to any potential problems with placement of the electrode array.

- *Post-operative management*
  - All external equipment should be inspected for proper function because external device issues can be mistaken for internal device malfunctions.
  - Impedance telemetry is a measure of the resistance to the flow of electrical current through a medium, and it helps determine whether appropriate current is being delivered by the device. Such testing should be performed during each mapping session, and the results should be evaluated for changes over time.
  - Although preoperative assessment of speech recognition provides a baseline for post-operative comparison (and helps determine anticipated levels of performance), post-operative assessments are an essential component of patient management and should be performed to determine whether the patient meets expected levels of performance, whether performance has decreased over time, and whether reasons other than a device malfunction can explain why performance is poorer than expected or has declined. Test batteries should be sensitive enough to detect small changes over time and might include both speech/language measures and speech perception tests.

Clinicians should be aware of several signs that might indicate that further investigation is required:

- Reduced speech recognition or speech/language skills or failure to meet expected levels of performance on formal test measures
- Reduced speech intelligibility or speech/language skills reported by a parent, a teacher, or the child's speech language pathologist
- Static or a buzzing sound with the device on or off
- Pain or discomfort with electrical stimulation that cannot be eliminated with changes to the clinical programming
- A strong change in behavior associated with device use, such as refusal to wear the device when the patient was previously compliant
- Intermittent loss of connectivity between the receiver and the electrode array
- Gradual disconnection or short circuiting of more than one electrodes in the array
- Frequent or intermittent perception of "popping" sounds
- Intermittent surges in loudness that exceed the loudness levels set by the clinician
- Intermittent or consistent decreases in speech quality

Clinicians can take several steps when a device failure is suspected:

- Exchange all external equipment with functioning equipment to confirm that the concerns are not caused by problems with external equipment.
- Request that an integrity test be performed by the device manufacturer because the manufacturer is able to perform testing that cannot be performed by most clinics and the manufacturer might be able to provide recommendations that can improve performance.
- Review the preoperative test results and patient demographics to determine whether the reduced performance can be explained by factors other than device malfunction.
- Reprogram the internal device to deactivate any electrodes that appear to have a negative effect on performance, and reevaluate performance to determine whether the reprogramming has improved performance. If performance does not improve, the clinician should request an integrity test.

A decision to explant/reimplant includes consideration of the risks associated with such surgery and the possible outcome:

- Surgical risks are similar to those associated with the initial implantation of a cochlear implant and include risks associated with general anesthesia, risks to the facial nerve, meningitis, cerebrospinal fluid leakage, perilymph fluid leakage, infection of the skin wound, blood or fluid collection at the implant site, post-operative dizziness or vertigo, tinnitus, taste disturbances, numbness around the incision, reparative granuloma, and other unforeseen complications (www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/CochlearImplants/ucm062843.htm).
- Performance risk includes the possibility of reduced performance with the replacement device.

When scheduling an explantation/reimplantation, clinicians might want to consider the following:

- For hard failures of the device, such surgery is often performed as soon as possible; limiting the amount of time without the device will limit the amount of time the patient is without sound.
- The activation may be expedited in order to decrease the amount of time the patient is without sound.
- The patient should be advised of the possible financial impact (expenses not covered by warranty) of the explantation/reimplantation.

Annex B
(informative)

Clinical checklist prior to explantation
Signs and symptoms checklist

The following checklist must be completed by clinicians to ensure complete consideration of the steps that should be taken to evaluate device function and to note signs and symptoms that could be related to malfunction of a cochlear implant. This information must be shared with the device manufacturer prior to device explantation, and an explant kit must be obtained from the manufacturer prior to explantation.

Clinician(s) completing report			
Date completed			
Patient ID			
Initial implant surgery date			
Explanted device make/model		Serial #:	

Please indicate below the reason(s) for considering device explant *(check all that apply):*

	Clear device malfunction (complete loss of sound/connectivity with internal device)
	Poor performance from onset of device use
	Decreased performance over time
	Plateau in performance following initial progression
	Changes in psychophysical responses to electrical stimulation
	Patient report of extraneous noises when using the device
	Please describe:
	Tinnitus that appears to be caused by device use
	Patient report of pain or discomfort with electrical stimulation that cannot be eliminated with changes to
	Dizziness associated with device use
	Strong change in behavior associated with device use, such as refusal to wear the device when patient was
	Inability of the internal receiver to maintain RF lock with the external speech processor
	Intermittent loss of connectivity between the receiver and the electrode array
	Abnormally high or low impedances on one or more electrodes in the array
	Intermittent surges in loudness that exceed the loudness levels set by the clinician
	Patient report of intermittent or consistent decreases in speech quality
	Medical reason
	Please specify:
	Other:

Was the manufacturer representative contacted prior to explantation?

☐ Yes
☐ No, please explain _____

Was integrity testing performed by the device manufacturer?

☐ Yes
☐ No

If yes, did the manufacturer determine that the device failed prior to explantation?

☐ Yes
☐ No
☐ Inconclusive

Was an explant kit obtained and made available for the explantation?

☐ Yes
☐ No

Please document that the following has taken place *(continue on the next page):*

	The release-of-medical-information form has been completed so that patient information can be shared with device manufacturer.	
	Poor, decreased, or change in performance has been documented using recorded speech perception measures.	
	For children, poor, decreased, or change in performance has been documented via speech/language evaluation.	
	Troubleshooting of all external components has been performed to rule out contributions of external equipment problems.	
	The device manufacturer has been contacted to discuss concerns, perform integrity testing, review mapping data, and obtain clinical recommendations/suggestions.	
	Objective measures have been performed, and the results have been compared to those obtained previously (at baseline).	
	Impedance testing has been performed, and the results have been compared to those obtained previously.	
	An X-ray or CT scan was performed to evaluate placement of the electrode array and receiver/stimulator.	
	Preoperative test results and patient demographics were reviewed to determine if reduced performance might be explained by factors other than device malfunction.	
	Reprogramming of the internal device was performed, including deactivation of any electrodes that appear to have a negative effect on performance. Performance was then re-evaluated to determine if reprogramming resulted in improved performance.	
	Please indicate if the poor/reduced performance could be attributed to any of the following:	
		Etiology of hearing loss
		Recent health changes, changes in medication, or other otologic symptoms

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

		Unreliable responses to speech processor programming
		Lack of, resistance to, or intermittent device use
		Facial nerve stimulation or lack of response on several electrodes
		Recent head trauma to the area of the device
		Recent notable electrostatic discharge (static shock) to the patient or the equipment

Please document the medical reason for device explant:

	Sustained poor performance
	Electrode migration
	Misplaced electrode array
	Facial nerve stimulation
	Shocking with device *ON*
	Shocking with device *OFF*
	Pain with device *ON* Location (e.g., deep in ear/head, over implant stimulator, ear canal, neck, etc.): _____ _____
	Pain with device *OFF* Location (e.g., scalp, flap, incision line, ear canal, neck, etc.): _____ _____

SURGICAL OBSERVATIONS (during device explant)

Were there any physically apparent signs of device failure prior to removal?

	Yes, please describe	
	No	

Electrode status: Did the electrode appear to have moved since initial placement?

	Yes, please describe	
	No	

Was there any evidence of infection or tissue reaction?

	Yes, please describe	
	No	

Was a device reimplanted?

	Yes, make, model, and serial number	
	No	

If yes, please describe the surgical placement of the second device:

	Appears similar to placement of the first device
	Inserted with little or no difficulty
	Met with some resistance but a full insertion was accomplished
	Second device incompletely inserted
	Other:

Will the explanted device be returned to the manufacture?

	Yes	
	No, please explain	

Please note: In order for the device manufacturer to perform appropriate testing on the device, the entire device should be returned to the device manufacturer, even if it has been severed or damaged during explant. Please return the electrode array, even if it has been disconnected from the implant, and please take special care to minimize the explanted device's exposure to cautery, mechanical shock, or electrostatic discharge when explanting and preparing the device for return to the manufacturer.

Signature_____ **Date** _____

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Annex C
(informative)

Returned implant analysis

The following template is provided for informative purposes to indicate how a manufacturer's analysis report might reflect the full device analysis performed to achieve final device classification. See Section 10.2.

Analysis of Returned Device

Serial number:

Complaint file:

Model:

Recipient		Current Status: Child/Adult	Reporting Status: Child (<10 y.o.) at Implantation Adult
Date of Birth		Clinic	

Manufacture Date		Implantation Date	
Regulatory Authority Report Date		Explantation Date	
		Period of Use (days)	

Summary Analysis and Classification Information

Date Received by Manufacturer	
Analysis Category	UME – Unrelated medical explant DBE – Depleted battery within designed time window EUE – Elective Upgrade Explant MRE - Medical reason for explant DFE - Device failure explant INC - Inconclusive failure analysis
Primary Failure Mode for MRE and DFE	
MDR Code	
Included in CFR calculation	Yes No
If No, provide rationale	
Other Observations during Failure Analysis:	
Comment	

Outcome of Investigation:

Analysis by: _____

Date of Analysis Completion:

Approved by: _____

Date of Approval:

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Background Information Provided

Surgical Information

[For surgical returns, enter reason for device explant.]

Clinical Information

[For explanted devices, enter background information including performance.]

In-situ Test Results

[For explanted devices, enter results of integrity (IT) tests, imaging, etc.]

Details of Analysis Performed

Non-Destructive Analysis – Inspection of the Implant (all medical and non-medical explants)

Process	Results
Visual inspection, including detailed electron microscopy or high-resolution microscopy if applicable, was conducted to assess the condition of the implant body and antenna coil.	• e.g., Damage consistent with [attempted implantation/ explantation] • e.g., Damage consistent with patient fall reported in clinical history • e.g., No anomalies observed
Visual inspection, including detailed electron microscopy or high-resolution microscopy if applicable, was conducted to assess the condition of the electrode leads.	• e.g., Bends and kinks consistent with [attempted implantation/explantation] • e.g., Cut/nick observed in lead and/or fantail • e.g., No anomalies observed
X-ray inspection was conducted to look for any physical anomalies inside the stimulator body, antenna coil, and electrode wires prior to any destructive tests.	• e.g., Loose component observed • e.g., Broken or shorted wire bond observed • e.g., No anomalies observed

Non-Destructive Analysis – Basic Electrical Tests – Link integrity

Process	Results
Electrical telemetry testing was conducted to confirm correct communication between the implant and sound processor.	• e.g., Normal communication confirmed • e.g., Linkage confirmed over specification coupling distances • e.g., Intermittent linkage observed at elevated test temperature • e.g., No telemetry linkage obtained consistent with clinical report

Non-Destructive Analysis – Basic Electrical Tests – Basic functionality testing

Process	Results
Electrical telemetry testing was conducted to perform implant test and diagnostics, as applicable.	• e.g., Normal diagnostics confirmed • e.g., Implant test measures out of specification • e.g., Implant functioning to specification
Basic electrical testing could not be performed due to severed electrode lead	• e.g., Electrical testing deferred to destructive analysis phase with case open

Non-Destructive Analysis – Basic Electrical Tests – Simulated clinical testing (shall include saline bath immersion)

Process	Results
The programming software was used to confirm communication with the sound processor and to detect any short or open circuits by measuring impedances.	• e.g., Normal communication confirmed • e.g., No short or open circuits detected • e.g., Impedances measured with on-board device telemetry within range for clinically relevant load conditions
Functional testing conducted to assess implant functionality through measuring device output after a stimulus command (only possible if electrode array was returned)	• e.g., Output waveform unbalanced • e.g., Measured output levels inconsistent with commanded stimulus • e.g., Normal implant function confirmed
Device tested according to device integrity testing protocol used in field evaluation	• e.g., Field test results replicated • e.g., Initial laboratory test results differed from field integrity assessment

Non-Destructive Analysis – Inspection of Manufacturing Records

Process	Results
Manufacturing records were checked to ensure compliance to quality system procedures and processes for any anomalies and reliability test data, lot acceptance test data, and screening data, as appropriate.	• e.g., Compliance confirmed • e.g., Summary of relevant data found

Non-Destructive Analysis – Advanced Inspection Tests

Advanced inspection methods (i.e., scanning electron microscopy (SEM), optical microscopy)	• e.g., Case crack, broken welds, etc., visualized

Non-Destructive Analysis – Advanced Electrical Tests

Process	Results
Tests were conducted to check for device intermittency by subjecting the device to stress: e.g., physical manipulation, temperature cycling, and ultrasonic vibration.	• e.g., Continuous normal operation observed • e.g., Transient waveform output observed. • e.g., Transient interruption in stimulation output or linkage
Tests were conducted to detect any current leakage from the implant electronic assembly to the electrodes in a powered state	• e.g., Electrical leakage during powered state in excess of specification • e.g., Electrical leakage current within specification
Functional testing was conducted to assess implant functionality by measuring device output during power-up/power-down transitions (only possible if electrode array was returned)	• e.g., Anomalous transient glitch seen on power start-up consistent with clinical report of somatic/acoustic sensation with headpiece placement • e.g., Normal implant function confirmed
Functional testing was conducted to test implant functionality by measuring the response to a stimulus.	• e.g., Normal telemetry system function confirmed

Non-Destructive Analysis – Advanced Mechanical Tests

Process	Results
Temperature cycling, heat soak, etc.	• Results of standard tests conducted under extreme conditions, etc.
Mechanical vibration	• Results of standard tests conducted under extreme conditions, etc.
Saline soak, etc.	• Results of standard tests conducted under extreme conditions, etc.
Combinations of above conditions	• Results of standard tests conducted under extreme conditions, etc.

Non-Destructive Analysis – Advanced Tests for Continuity and Impedance

Process	Results
Continuity testing (diagnose for opens, shorts, impedances). The testing includes saline bath immersion even if the electrode array is not present because this procedure can provide information about moisture ingress into the non-hermetic side of feed-throughs.	• e.g., Results within specification • e.g., Results suggestive of possible bridge pathway between contacts

Non-Destructive Analysis – Advanced Tests for Hermeticity

Process	Results
Fine leak test	PASS FAIL NOT PERFORMED

Destructive Analysis – Residual Gas Analysis (RGA)

Process	Results
Gross leak test	PASS FAIL NOT PERFORMED
Residual gas analysis (RGA) testing	PASS FAIL NOT PERFORMED
Analysis results	Measured values: ___% Water *Pass Criteria: < specification limit % Water*
Acceptance criteria	• e.g., 5,000 ppm water vapor • e.g., Manufacturer criteria based upon engineering analysis and test data for this implant model – Ref Doc _____

Destructive Analysis – Cover Removed – Measurement of Signals Related to Transcutaneous/Percutaneous Link

Process	Results
RF tuning of transcutaneous link	• e.g., Forward and backward telemetry links within specification

Destructive Analysis – Cover Removed – Measurement of Output Waveforms at Feed-through Pins

Process	Results
Recordings of waveforms at feed-throughs	• e.g., Within specifications for commanded test signals

Destructive Analysis – Cover Removed – Detailed Inspection and Testing of Electronic Assembly

Process	Results
Detailed inspection of electronic assembly	• e.g., ASIC for signs of failure such as cracks • e.g., Moisture leakage path • e.g., Corrosion products • e.g., Manufacturing defects • e.g., Wire bond short or broken • e.g., Other
Discrete components, such as resistors, capacitors, diodes, active devices etc., out of specification	• e.g., Specific component failure (could be related to ESD below)
Identification of ESD failure	• e.g., Test results consistent with known failure modes caused by ESD exposures.

Destructive Analysis – Cover Removed – Determination of Failure Site and Mode or Inconclusive Finding

Process	Results
Failure site	• Conclusive location or reason for failure
Failure mode	• Specific failure mode per standard
Failure mode comments	• Additional comments/explanation
INCONCLUSIVE ANALYSIS	• Justification of inconclusive finding

Annex D
(informative)

Indications of performance decline

Common symptom categories include, but are not limited, to the following:

a) Abnormal sound percepts
   i. Unusual sounds that cannot be explained by sounds in the environment
   ii. Loud bursts of sound percepts
   iii. Other abnormal sound percept (specify)

b) Pain
   i. Pain over the implant site
   ii. Pain or discomfort radiating down the neck
   iii. Shocks with device use
   iv. Burning sensation at the implant site
   v. Itching at the implant site
   vi. Pain along distribution of the fifth cranial nerve (trigeminal nerve)
   vii. Other pain (specify)

c) Documented performance decrement
   i. Sudden loss of auditory ability
   ii. Decrement in hearing over time or lack of expected progress according to speech perception measures
   iii. Intermittent auditory percept
   iv. Failure to meet predicted performance level
   v. Reduction in or lack of meaningful speech understanding
   vi. Lack of sound clarity
   vii. Necessity for deactivating electrodes over time
   viii. Implant magnet issues (loss of magnet adhesion)
   ix. Regression in language and speech
   x. Deterioration of or plateau in academic performance
   xi. Decline in verbalization
   xii. Other performance decline (specify)

d) Medical issues
   i. Infection
   ii. Meningitis
   iii. Vertigo or disequilibrium
   iv. Wound breakdown
   v. Headaches
   vi. Swelling at the implant site
   vii. Otorrhea
   viii. Facial twitching with implant operating
   ix. Other medical issues (specify)

e) Behavioral issues, especially in pediatric cases
   i. Increase in “bad” behavior
   ii. Aggressiveness
   iii. Unwillingness to wear the device
   iv. Head hitting
   v. Inattentiveness
   vi. Being frequently “off task”
   vii. Other behavioral issues (specify)

f) Other general observations (specify)

Annex E
(informative)

Reliability reporting to regulatory bodies

This Annex contains examples of how reliability data are to be reported to regulatory bodies in accordance with the requirements of Section 11.4.2. The examples include the following:

a) Acceptable graphical presentations of implant reliability data for 12-month analysis intervals. For brevity, the graphs shown only use 12-month analysis intervals and represent the limited publicly reported data. However, for compliance with this standard, data shall also be analyzed and graphed using three-month analysis intervals and 12-month analysis intervals, in accordance with the requirements of this standard.
b) Acceptable tabular presentations of implant reliability variables for-three-month and 12-month analysis intervals.

Regulatory graphical and tabular reports will be proprietary to the manufacturer and not available to the public.

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Example a)

Acceptable graphical presentations

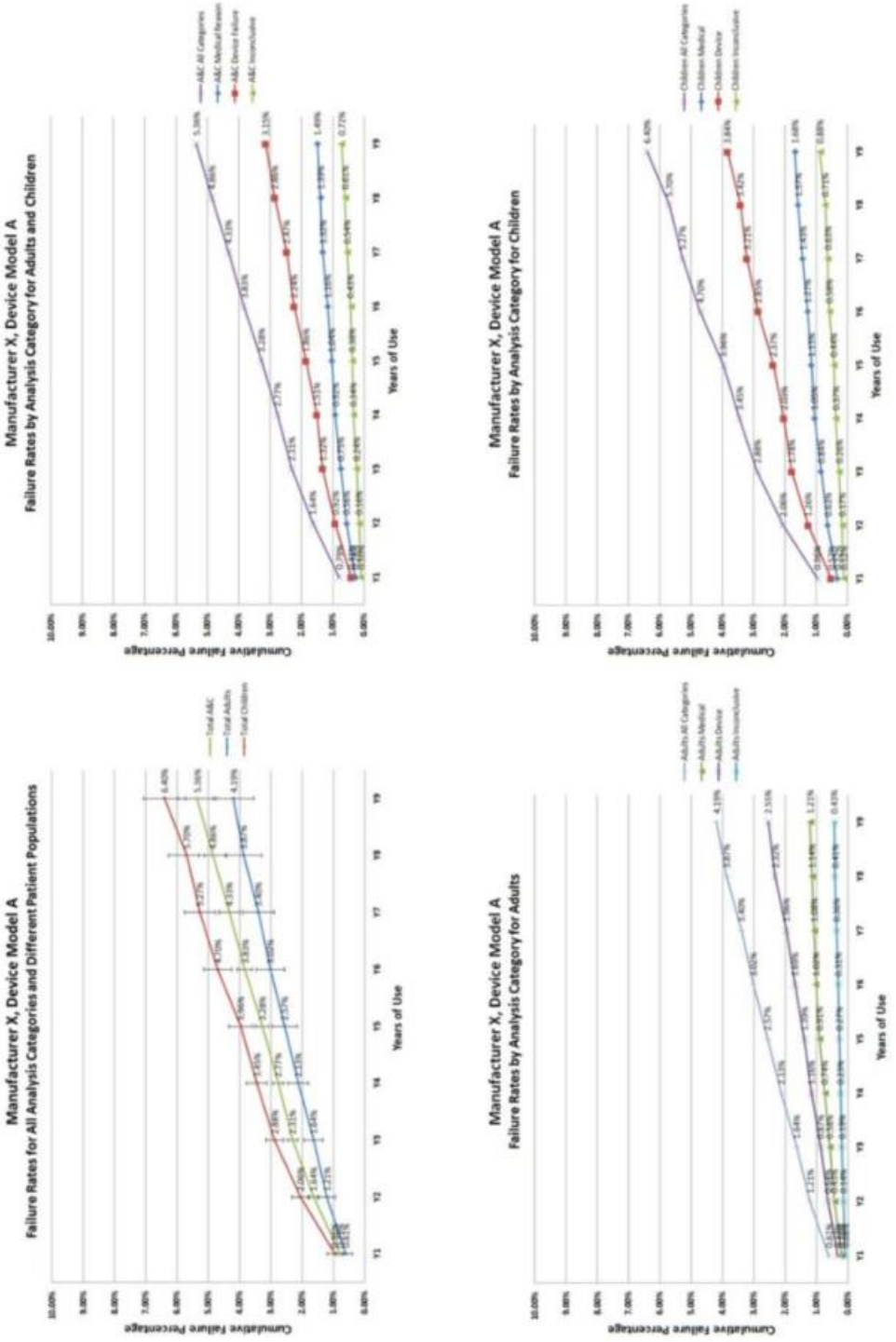


Figure E.1—Acceptable graphical representations of implant reliability data

Example b)

Survival Analysis Data Reporting per AAMI Section 11.4.2.2 (3-month analysis intervals)

Panel 1 of 3

Device model [Note 1]: _____
Reporting date: _____
Date model first implanted: _____
Total Analysis Intervals [TOT_INTERVALS] [Note 2]: _____
Confidence interval criteria and calculation method details: _____

ALL Patients (ADULT AND PEDIATRIC)	3-month analysis intervals since device model first implanted						
	1	2	3	4	...	TOT_INTERVALS - 1	TOT_INTERVALS
N ‡ Note 3							
A ‡							
D ‡							
L ‡							
OA ‡							
DBE ‡							
EUE ‡							
UME ‡							
MRE ‡							
DFE ‡							
INC ‡							
CFP_{MRE} *							
UB of CI for CFP_{MRE} *							
LB of CI for CFP_{MRE} *							
CFP_{DFE} *							
UB of CI for CFP_{DFE} *							
LB of CI for CFP_{DFE} *							
CFP_{INC} *							
UB of CI for CFP_{INC} *							
LB of CI for CFP_{INC} *							
CFP_{TOT} * Note 4							
UB of CI for CFP_{TOT} *							
LB of CI for CFP_{TOT} *							

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Survival Analysis Data Reporting per AAMI Section 11.4.2.2 (3-month analysis intervals) [continued] **Panel 2 of 3**

ADULT Patients Only (Patients ≥ 10 years old)	3-month analysis intervals since device model first implanted						
	1	2	3	4	...	TOT_INTERVALS - 1	TOT_INTERVALS
N ‡ Note 3							
A ‡							
D ‡							
L ‡							
OA ‡							
DBE ‡							
EUE ‡							
UME ‡							
MRE ‡							
DFE ‡							
INC ‡							
CFP_{MRE} *							
UB of CI for CFP_{MRE} *							
LB of CI for CFP_{MRE} *							
CFP_{DFE} *							
UB of CI for CFP_{DFE} *							
LB of CI for CFP_{DFE} *							
CFP_{INC} *							
UB of CI for CFP_{INC} *							
LB of CI for CFP_{INC} *							
CFP_{TOT} * Note 4							
UB of CI for CFP_{TOT} *							
LB of CI for CFP_{TOT} *							

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Survival Analysis Data Reporting per AAMI Section 11.4.2.2 (3-month analysis intervals) [continued] **Panel 3 of 3**

PEDIATRIC Patients Only (Patients < 10 years old)	**3-month analysis intervals since device model first implanted**						
	1	**2**	**3**	**4**	**...**	**TOT_INTERVALS - 1**	**TOT_INTERVALS**
N ‡ Note 3							
A ‡							
D ‡							
L ‡							
OA ‡							
DBE ‡							
EUE ‡							
UME ‡							
MRE ‡							
DFE ‡							
INC ‡							
CFP_{MRE} *							
UB of CI for CFP_{MRE} *							
LB of CI for CFP_{MRE} *							
CFP_{DFE} *							
UB of CI for CFP_{DFE} *							
LB of CI for CFP_{DFE} *							
CFP_{INC} *							
UB of CI for CFP_{INC} *							
LB of CI for CFP_{INC} *							
CFP_{TOT} * Note 4							
UB of CI for CFP_{TOT} *							
LB of CI for CFP_{TOT} *							

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Survival Analysis Data Reporting per AAMI Section 11.4.2.2
(12-month analysis intervals)

Device model [Note 1]: _____
Reporting date: _____
Date model first implanted: _____
Total Analysis Intervals (TOT_INTERVALS) [Note 2]: _____
Confidence interval criteria and calculation method details: _____

ALL Patients (ADULT AND PEDIATRIC)	12-month analysis intervals since device model first implanted						
	1	2	3	4	...	TOT_INTERVALS - 1	TOT_INTERVALS
N ‡ Note 3							
A ‡							
D ‡							
L ‡							
OA ‡							
DBE ‡							
EUE ‡							
UME ‡							
MRE ‡							
DFE ‡							
INC ‡							
CFP_{MRE} *							
UB of CI for CFP_{MRE} *							
LB of CI for CFP_{MRE} *							
CFP_{DFE} *							
UB of CI for CFP_{DFE} *							
LB of CI for CFP_{DFE} *							
CFP_{INC} *							
UB of CI for CFP_{INC} *							
LB of CI for CFP_{INC} *							
CFP_{TOT} * Note 4							
UB of CI for CFP_{TOT} *							
LB of CI for CFP_{TOT} *							

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Survival Analysis Data Reporting per AAMI Section 11.4.2.2 (12-month analysis intervals) [continued] Panel 2 of 3

ADULT Patients Only (Patients ≥ 10 years old)	12-month analysis intervals since device model first implanted						
	1	2	3	4	...	TOT_INTERVALS - 1	TOT_INTERVALS
N ‡ Note 3							
A ‡							
D ‡							
L ‡							
OA ‡							
DBE ‡							
EUE ‡							
UME ‡							
MRE ‡							
DFE ‡							
INC ‡							
CFP_{MRE} *							
UB of CI for CFP_{MRE} *							
LB of CI for CFP_{MRE} *							
CFP_{DFE} *							
UB of CI for CFP_{DFE} *							
LB of CI for CFP_{DFE} *							
CFP_{INC} *							
UB of CI for CFP_{INC} *							
LB of CI for CFP_{INC} *							
CFP_{TOT} * Note 4							
UB of CI for CFP_{TOT} *							
LB of CI for CFP_{TOT} *							

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

PEDIATRIC Patients Only (Patients < 10 years old)	12-month analysis intervals since device model first implanted						
	1	2	3	4	...	TOT_INTERVALS - 1	TOT_INTERVALS
N ‡ Note 3							
A ‡							
D ‡							
L ‡							
OA ‡							
DBE ‡							
EUE ‡							
UME ‡							
MRE ‡							
DFE ‡							
INC ‡							
CFP_{MRE} *							
UB of CI for CFP_{MRE} *							
LB of CI for CFP_{MRE} *							
CFP_{DFE} *							
UB of CI for CFP_{DFE} *							
LB of CI for CFP_{DFE} *							
CFP_{INC} *							
UB of CI for CFP_{INC} *							
LB of CI for CFP_{INC} *							
CFP_{TOT} * Note 4							
UB of CI for CFP_{TOT} *							
LB of CI for CFP_{TOT} *							

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

‡ integer format

* decimal to ≥4 significant digits with ≥2 decimal places

UB of CI = Upper Bound of Confidence Interval

LB of CI = Lower Bound of Confidence Interval

NOTE 1—Include model of receiver/stimulator when aggregating across available arrays, OR model of array type when aggregating across available receiver/stimulators. If aggregating across arrays for a given receiver/stimulator, list the particular arrays. If aggregating across receiver/stimulators for a given array, list the particular receiver/stimulators.

NOTE 2a—TOT_INTERVALS equals the number of complete 3-month intervals between the date that the device was first implanted to the cutoff date, which is either the end of the calendar year or the end of the second quarter (Section 11.4.1).

NOTE 2b—TOT_INTERVALS equals the number of complete 12-month intervals between the date that the device was first implanted to the cutoff date, which is either the end of the calendar year or the end of the second quarter (Section 11.4.1).

NOTE 3—Variables are defined in Section 11.

NOTE 4:—TOT = MRE + DFE + INC

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Annex F
(informative)

Pareto analysis

This Annex provides more information about Pareto analysis (Section 11.4.2.3).

Pareto analysis is a technique used for decision-making. Based on the "Pareto Principle," known as the 80/20 rule, Pareto analysis statistically separates a limited number of input factors according to their impact on an outcome, either desirable or undesirable. For reliability purposes, it can be used to rank failure mechanisms identified from root cause analysis. After the causal factors are identified, they are ranked from the most frequent to the least frequent and converted to a cumulative percentage that is then plotted to determine each failure mechanism's contribution to 80 % of the failures. Resolving the key factors associated with the top 80 % of the failures might also eliminate the majority, if not all, of the remaining less important factors contributing to product failure. In other words, the analysis helps to identify the top 20 % of causes that must be addressed so that potentially 80 % or more of the problems can be resolved.

The following steps are taken to identify the important causes using Pareto analysis:

1) Form an explicit table listing failure causes and their frequency as a percentage.
2) Arrange the rows in decreasing order of importance of the causes (i.e., the most important cause first).
3) Add a cumulative percentage column to the table.
4) Plot the causes on the *x*-axis and the cumulative percentage on the *y*-axis.
5) Join the above points to form a curve.
6) Plot (on the same graph) a bar graph with causes on the *x*-axis and percent frequency on the *y*-axis.
7) Draw a line at 80 % on the *y*-axis, parallel to the *x*-axis. Then drop the line at the point of intersection with the curve on the *x*-axis. This point on the *x*-axis separates the important causes (on the left) from the trivial causes (on the right).
8) Explicitly review the chart to ensure that at least 80 % of the causes are captured.

Table F.1 is an exemplar report of device-related failure causes ranked by importance (relative percent) with the associated cumulative percentages.

Figure F.1 is an exemplar graphic comparing the device-related failure categories listed in Table F.1. The columns represent the relative percent of explants per failure category and the line-plus-symbol plot shows the cumulative percentage of explants across explant category.

Table F.1—Device problems contributing to explantation, with associated normalized relative percent and cumulative percentage data (fictitious data)

Device problem	Normalized relative %	Cumulative %
RF electronics	0.34	34
Electrodes	0.25	59
Intermittent	0.2	79
Feed-through	0.13	92
Locking mechanism	0.05	97
PCB defect	0.03	100

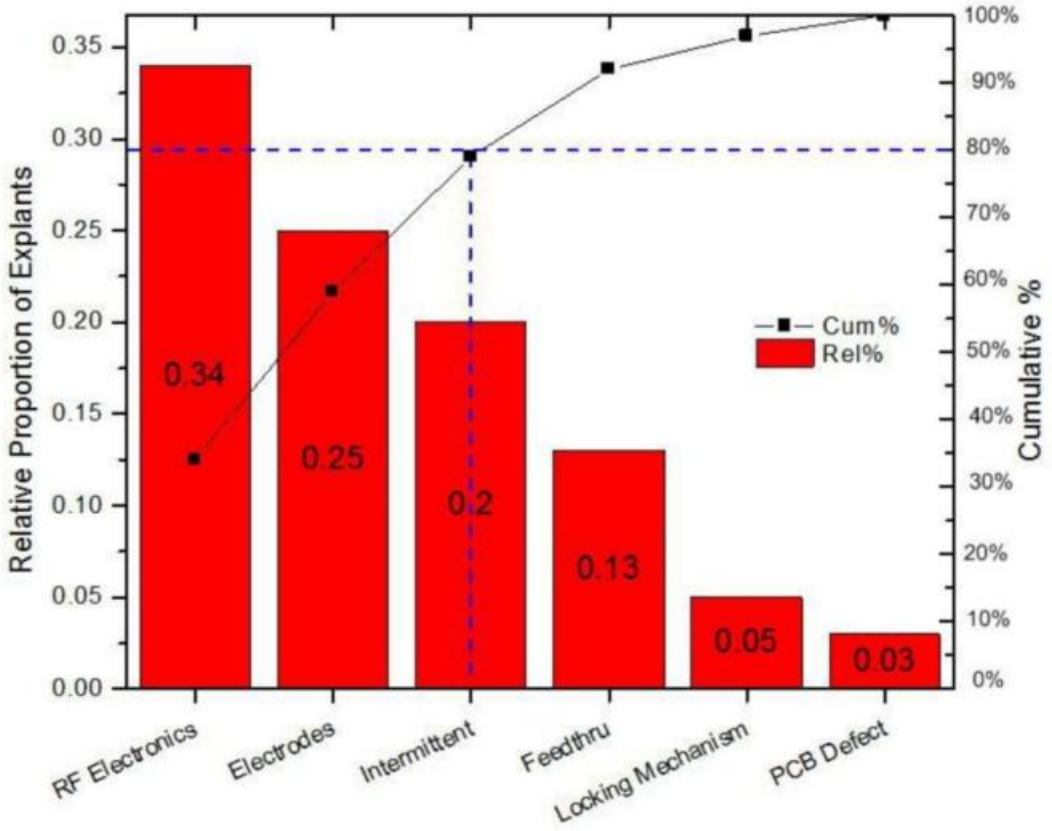


Figure F.1—Pareto plot of categories of device-related failures associated with the device explants reported in Table F.1 (fictitious data)

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Annex G
(informative)

Failed component return rate (FCRR) graphic and table

Figure G.1 and Table G.1 are examples of acceptable ways of presenting externals reliability data derived from actual field performance. The example data shown below are for a sound processor that has been on the market less than two years. See Section 11.4.3.2 for detailed requirements.

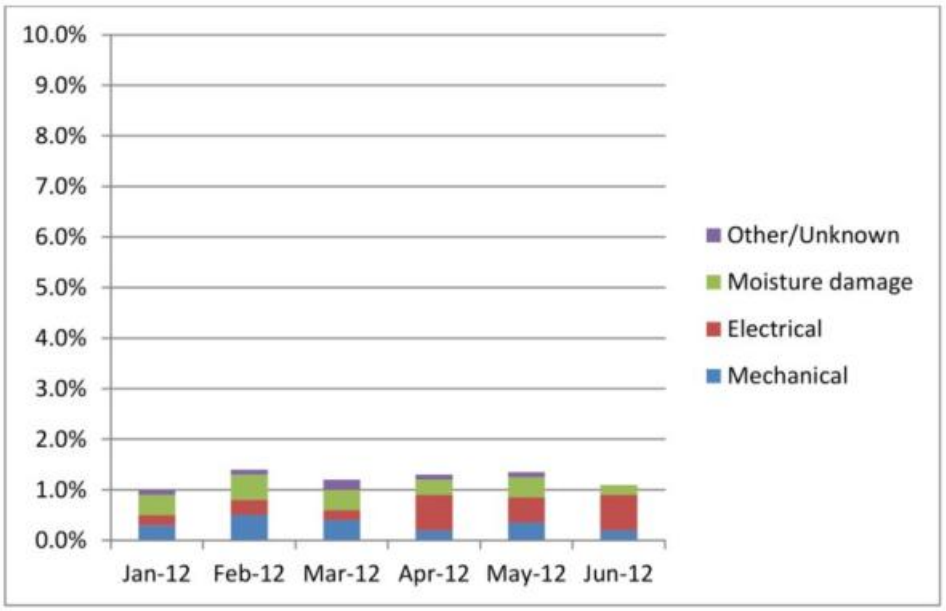


Figure G.1—Sample graph of externals reliability data

Table G.1—Sample table listing of externals reliability data

Fail Mode	Jan-12	Feb-12	Mar-12	Apr-12	May-12	Jun-12
Mechanical	0.3 %	0.5 %	0.4 %	0.2 %	0.4 %	0.2 %
Electrical	0.2 %	0.3 %	0.2 %	0.7 %	0.5 %	0.7 %
Moisture damage	0.4 %	0.5 %	0.4 %	0.3 %	0.4 %	0.2 %
Other/unknown	0.1 %	0.1 %	0.2 %	0.1 %	0.1 %	0.0 %
Fault-Free	0.4 %	0.3 %	0.4 %	0.5 %	0.3 %	0.2 %

The following example data are for a device model that has been on the market for more than 2 years.

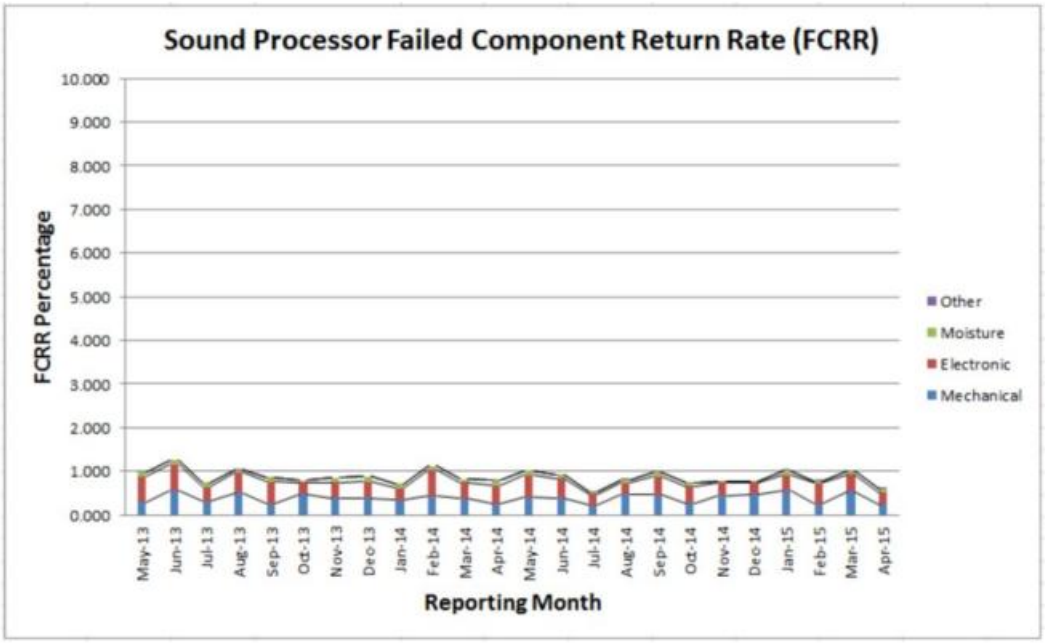


Figure G.2—Sample graph of externals reliability data

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Annex H
(informative)

Reliability reporting template for the public and clinical community

This Annex provides examples of acceptable presentations of implant reliability data, based on actual field performance, for the public and clinical community. See Section 11.5.2 for detailed requirements.

The Annex includes a common document that may be used by all manufacturers in describing reliability data. One set of hypothetical field data is included to illustrate the required graphical and tabular formats.

The next section provides the common document language recommended for use in labeling and marketing materials intended for current cochlear implant recipients, their family, or potential candidates.

"How to Read a Manufacturer's Reliability Report

"There are many things you should think about when choosing a cochlear implant for yourself or your child. One important factor is the reliability of the cochlear implant.

"In 2017, guidelines were approved (ANSI/AAMI C186) that outline procedures that manufacturers should follow when reporting the reliability of cochlear implants. The guidelines require manufacturers provide information to the public about the percentage of implanted devices that have been removed following implantation. This number is the cumulative removal percentage, or CRP.

"The CRP provides information regarding the reliability of a certain make and model of implant over time. The CRP for a given device is approximately the percentage of the total number of removed devices compared to the total number of implanted devices of the same make, model and similar duration of use. For example, if the CRP after 5 years of experience with a specific implant model is 7%, this means that after 5 years, the patient's chance of obtaining continued benefit from the cochlear implant system, as described for its intended use, is 93%. In other words, after this period of time, 7% of treatments with the cochlear implant system will have failed for various reasons. Section 11 of the ANSI/AAMI CI86 guidelines describes how devices are analyzed as part of the process for determining the CRP.

"It is important to track device reliability information over time because cochlear implants typically remain implanted for years. It is also important to track the reasons for removal when devices are replaced. The guidelines recommend that manufacturers report the worldwide CRP for each make and model of cochlear implant device sold in the U.S. The CRP classifies removed devices into three different categories that define the reason for removal: medical, non-medical, and inconclusive. Examples of medical reasons for device removal include infection, rejection of the device due to allergy, or improper positioning of the internal device. Examples of non-medical reasons for device removal include suspected implant failure due to mechanical or electronic issues, moisture damage, or other problems that could affect device function. Occasionally, manufacturer testing of the device indicates no fault found with the device, despite a reason for removal. For example, a patient experiences pain with device use or unexplained performance decline, but manufacturer testing of the explanted device reveals normal function. Such cases are placed in the medical category.

"Age-related differences may affect the CRP. Therefore, data are also shown for patients who are both older (10 years of age or older) and younger (younger than 10 years of age) at the time they received the implant. Typically, children younger than 10 years of age have a higher chance of activity-related damage to the device.

"You will note that no implant device has perfect reliability over time. You are encouraged to discuss concerns and questions you have about device reliability with your hearing professional.

"Hearing professionals will regularly verify that the implant site remains healthy and they will check that the device is working properly. This is usually done through frequent physical exams, monitoring of sound processor programming, and testing hearing performance. In some cases, the hearing professional may ask the device manufacturer to

perform additional testing to help determine if a device is not working properly. Removal of the device may be recommended when certain medical or device-related problems occur.

"If a cochlear implant is removed, the surgeon returns the device to the implant manufacturer for testing. If the manufacturer finds that the device is not working properly, additional tests are performed to determine the cause of the failure. Once testing is complete, the results are sent to the hearing professional and the manufacturer's reliability report is updated. As part of the requirements of ANSI/AAMI CI86, device manufacturers send detailed reliability reports to the U.S. Food and Drug Administration (FDA) every six months. Frequently, the device manufacturer uses the results of these tests to improve the design of future products.

"The guidelines also require manufacturers to report the reliability of all models of sound processors sold in the U.S. The Failed Component Return Rate (FCRR) describes sound processor reliability. The manufacturer tests sound processors that have been returned to determine if they are working and, if not, why they failed. The FCRR is the percentage of the total number of failed processors received within the last month compared to the total number of the same processor sold in the U.S. by the end of that month.

"The manufacturers publish their updated reliability reports every six months. To ensure you have the most recent information, check the expiration date on the report. If expired, the most recent report is available at the manufacturer's website or is available from your hearing professional."

Example of Reliability Data

On the following pages, one set of hypothetical reliability data is presented. The data are an example and are not attributable to any particular manufacturer's device or any currently available device. The tabular and graphical formats are those required for reporting by all manufacturers in accordance with Section 11.5.2.

The data represent one hypothetical device that has been on the market for 9 years. The data are a reasonable example of what might be expected in real future data.

Table H.1—Example of hypothetical reliability data from *Manufacturer X* for Device *A*

Manufacturer	Manufacturer X																	
Device Model	COCHLEAR IMPLANT A																	
Year Introduced	20XX																	
Group (Adults, Children, Combined)	**Adults**						**Children**						**Combined Adults and Children**					
Subcategory (Medical Related, Device Failure, Inconclusive, Total)	Medical Related	Device Failure	Incon-clusive	Total	Total		Medical Related	Device Failure	Incon-clusive	Total	Total		Medical Related	Device Failure	Incon-clusive	Total	Total	
Years	CFP	CFP	CFP	CFP	CI_up	CI_low	CFP	CFP	CFP	CFP	CI_up	CI_low	CFP	CFP	CFP	CFP	CI_up	CI_low
Y1	0.20%	0.33%	0.08%	0.61%	0.23%	0.23%	0.32%	0.52%	0.12%	0.96%	0.21%	0.21%	0.28%	0.41%	0.10%	0.79%	0.12%	0.12%
Y2	0.43%	0.64%	0.14%	1.21%	0.26%	0.26%	0.63%	1.26%	0.17%	2.06%	0.26%	0.26%	0.56%	0.92%	0.16%	1.64%	0.14%	0.14%
Y3	0.58%	0.87%	0.19%	1.64%	0.29%	0.29%	0.84%	1.78%	0.26%	2.88%	0.30%	0.30%	0.75%	1.32%	0.24%	2.31%	0.16%	0.16%
Y4	0.74%	1.16%	0.23%	2.13%	0.33%	0.33%	1.05%	2.03%	0.37%	3.45%	0.34%	0.34%	0.92%	1.51%	0.34%	2.77%	0.18%	0.18%
Y5	0.91%	1.39%	0.27%	2.57%	0.38%	0.38%	1.15%	2.37%	0.44%	3.96%	0.40%	0.40%	1.04%	1.86%	0.38%	3.28%	0.21%	0.21%
Y6	1.02%	1.69%	0.31%	3.02%	0.44%	0.44%	1.27%	2.85%	0.58%	4.70%	0.46%	0.46%	1.16%	2.24%	0.43%	3.83%	0.24%	0.24%
Y7	1.08%	1.96%	0.36%	3.40%	0.50%	0.50%	1.43%	3.21%	0.63%	5.27%	0.51%	0.51%	1.32%	2.47%	0.54%	4.33%	0.33%	0.33%
Y8	1.14%	2.32%	0.41%	3.87%	0.58%	0.58%	1.57%	3.42%	0.71%	5.70%	0.58%	0.58%	1.39%	2.86%	0.61%	4.86%	0.45%	0.45%
Y9	1.21%	2.55%	0.43%	4.19%	0.67%	0.67%	1.68%	3.84%	0.88%	6.40%	0.65%	0.65%	1.49%	3.15%	0.72%	5.36%	0.61%	0.61%
	Note:																	
	CI_up and CI_low are 95% Confidence Limits																	

 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Acceptable graphical presentations

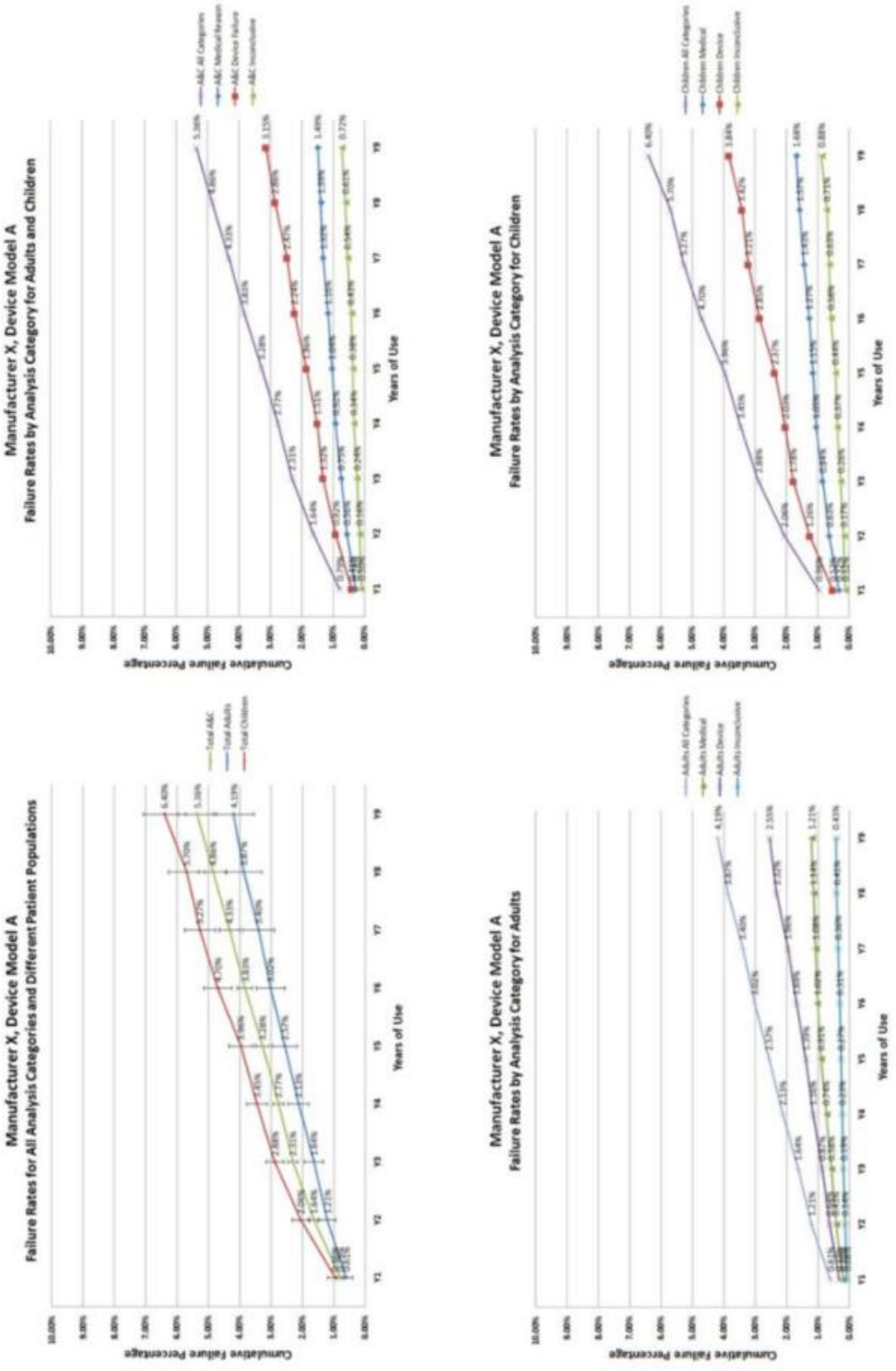


Figure H.1—Acceptable graphical representations of reliability data

Annex I
(informative)

Product specification data sheets

As required in Section 12.1, the accompanying documentation shall include information for public distribution regarding the general specifications of the medical device in the summary form of product data sheets. This Annex includes examples of the product data sheets listed below:

a) Table I.1—Manufacturer's implant specifications
b) Table I.2—Manufacturer's electrode specifications
c) Table I.3—Manufacturer's sound processing strategy
d) Table I.4—Manufacturer's sound processor specifications
e) Table I.5—Manufacturer's remote-control specifications

As these product data sheets are only meant to be examples, the suggested content is intended to be informative only. Section 12.1 and other sections of the standard specify the minimum required content.

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Table I.1—Manufacturer's implant specifications

Mechanical properties	
Weight	TBD g
Size	a) Volume mm^3 (excluding electrode) b) Surface area mm^2 (excluding electrode) a. Top side b. Bottom side c) Maximum thickness d) Maximum length (excluding electrode) e) Maximum width
Extra cochlear ground electrode(s)	List
Tissue-contacting materials	List
Electrical properties	
Output current	D to A resolution (TBD µA resolution)
Clinical unit	Definition (equation allowing conversion of clinical units to physical units; i.e., nC/phase, µs and/or µA)
Pulse width	TBD µs, automatically or manually programmable
Electrical output stimulation strategy	TBD (e.g., paired, sequential, bipolar, analog, charge-balancing methodology, source sink-grounding configuration)
Ratio of independent output circuits to independent output contacts	List
Maximum number of independent electrode contacts	List
Diagnostics	List
Telemetry efficiency	Minimum and maximum operating range of skin flap thickness; optimal skin flap thickness
MRI safety with implant magnet in place	This person is implanted with a *** device and may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction. Full MRI safety information is available in the MRI section of the physician manual, which can be obtained at www.***** or by calling *****." Contact manufacturer required prior to MRI: Y/N
MRI safety with implant magnet removed	List Static field strengths with MR Conditional approvals Contact manufacturer required prior to MRI: Y/N
Active/available electrodes	List
Compatible sound processors	List
Compatible headpieces	List (If there is a difference in telemetric efficiency, it should be described with the range and optimal distance)

Table I.2—Manufacturer's electrode specifications

Cochlear implant with electrode	
Construction	**Description**
Maximum width of the most apical electrode and at the most basal electrode	TBD mm – TBD mm
Number of electrically independent contacts	TBD
Active length	TBD mm
Specific surgical approach required	TBD
Minimum recommended cochleostomy size	TBD mm
Intended position in the cochlea	TBD
Markers	TBD
Special insertion tool required	Y/N, not applicable (or not necessary) Description
Insertion tool reusable for same electrode	Y/N, number of times Description

Table I.3—Manufacturer's sound processing strategy

Capture	
Audio processing frequency range	TBD Hz – TBD Hz
Clinical unit	Definition (equation allowing conversion to/from physical unit, i.e. nC/phase, uS and uA)
Minimal and maximum output range	0 µA – TBD µA (TBD µA resolution)
Input compression	Description
Output compression	Description
Envelope/Amplitude extraction	Description
Fine structure/Phase extraction	Description
Frequency analysis	Description
Sound amplitude coding of electrical output	Description
Pulse duration coding of intensity	Description
Pulse amplitude coding of intensity	Description
Spatial spread of simultaneous stimulation modulation and/or pulse rate coding of intensity	Description
Noise management	Description
Environmental/Awareness	If yes, describe features and how it impacts the system from the microphone to the output of the electrode

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Table I.4—Manufacturer's sound processor specifications

Properties	
Wearing options	TBD
Weight	TBD g
Size	Height = TBD mm Thickness = TBD mm Width = TBD mm Volume = TBD mm^3 Length = TBD mm Weight = TBD g
Color options	TBD
Number of microphones	TBD
Microphone frequency range	Description TBD Hz – TBD Hz, ~TBD dB SPL (A weighted) noise floor
Internal memory	TBD program slots, TBD kB memory
Available programs	TBD
Auxiliary input/output port	TBD
Program switches	TBD
Status indicator type	TBD
Volume/sensitivity controls	TBD
Alarms	TBD
Environmental	
Humidity range	TBD % – TBD %
Moisture resistance	TBD
Operating temperature range	TBD °C – TBD °C (non-condensing)
Storage temperature range	TBD °C – TBD °C
Power	
Battery options	Internal Y/N External Y/N List external battery options Weight of battery and processor
Battery operating time	List for all available options: average TBD, range TBD – TBD
Battery capacity	List for all available options: TBD % after TBD charges
Sound processing	
Audio sound capture	TBD Bandwidth (captured frequency range and sampling frequency, e.g., 100–8000 Hz, 16.4kHz sampling rate) Dynamic range (Bit resolution, e.g., 96 dB 16-bit resolution)
Input dynamic range (instantaneous)	TBD dB
Earhooks	Descriptions

Table I.4—*Continued*

Headpiece typesC	Descriptions
Number of headpiece magnets	TBD
Accessories	
Headpiece microphone frequency range	TBD Hz – TBD Hz, ~TBD dB SPL (A weighted) noise floor
Headpiece colors	TBD
Headpiece cable colors	TBD
Headpiece cable lengths	TBD cm
Accessories for loop systems	TBD
Accessories for telephone use	TBD
Remote controls	Y/N If yes, is dedicated hardware required?
Compatibility	
Implants	TBD

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Table I.5—Manufacturer's remote-control specifications

Mechanical properties	
Weight	TBD g
Size	Height = TBD mm Length = TBD mm Width = TBD mm
Electrical properties	
Operating modes	TBD
Display type	TBD
Controls	TBD
Connectors	TBD
Forward link distance	TBD cm
Back link distance	TBD cm
Power supply	
Battery type	TBD
Battery life monitor (remote control)	TBD
Battery life monitor (sound processor)	TBD
Configuration	
Software upgradable?	Y/N
Modes	Description
Environmental	
Humidity range	TBD % – TBD %
Moisture resistance	TBD
Operating temperature range	TBD °C – TBD °C
Storage Temperature Range	TBD °C – TBD °C
Compatibility	
Implant	TBD
Sound processor	TBD

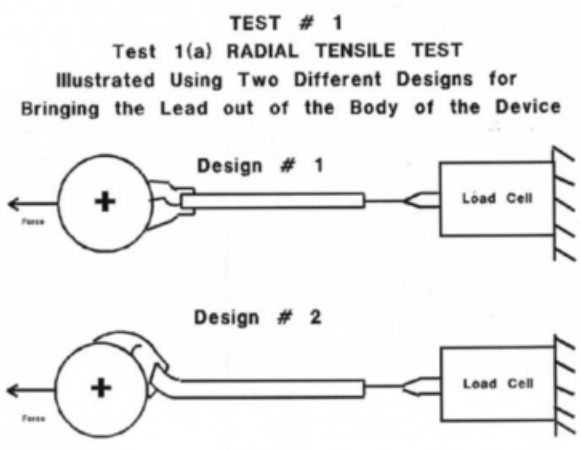
Annex J
(informative)

Mechanical testing of leads and interfaces to case bodies

This Annex presents various loading methods for the tensile testing of leads. Examples are given for two different designs, one which brings the lead out of the case body of the device in a manner symmetric to the case body and one which brings the lead out in a manner asymmetric to the case body. Manufacturers should consider such loading alternatives in the design of tensile force testing of leads (Section 23.1.6) and flexural testing of leads (Section 23.1.8), especially in relation to failures occurring in the vicinity of where the lead exits the case body.

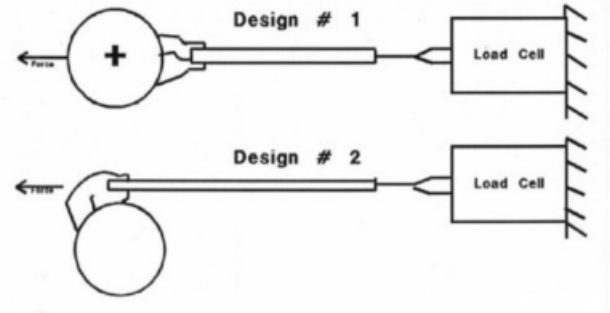
The examples given here illustrate various loading methods and should not be considered exclusive of other engineering test approaches determined to be best for a particular manufacturer's design. The examples included here are as follows:

Test 1a:	Radial tensile loading
Test 1b:	Tangential tensile loading
Test 1c:	Perpendicular tensile loading
Tests 2a and 2b:	Tensile loading at variable angular directions relative to the case body
Test 3	Shear loading of lead at case-body entry/exit zone
Test 4	Variation on radial tensional loading, combined with cyclic stretching of lead

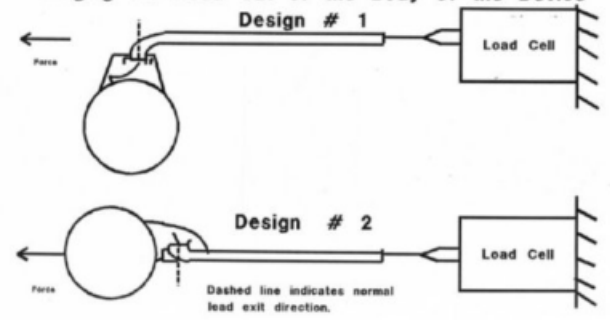


 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

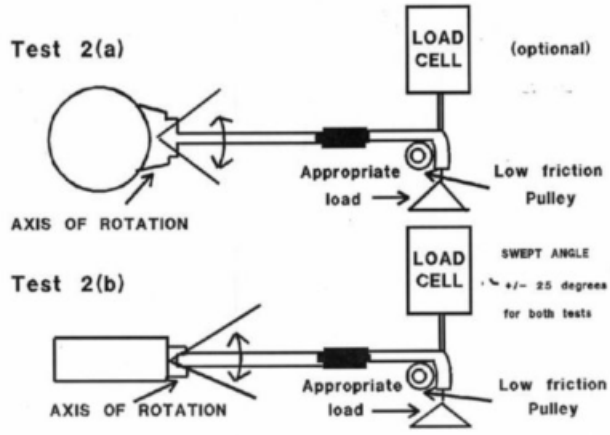
TEST # 1
Test 1(b) TANGENTIAL TENSILE TEST
Illustrated Using Two Different Designs for
Bringing the Lead Out of the Body of the Device

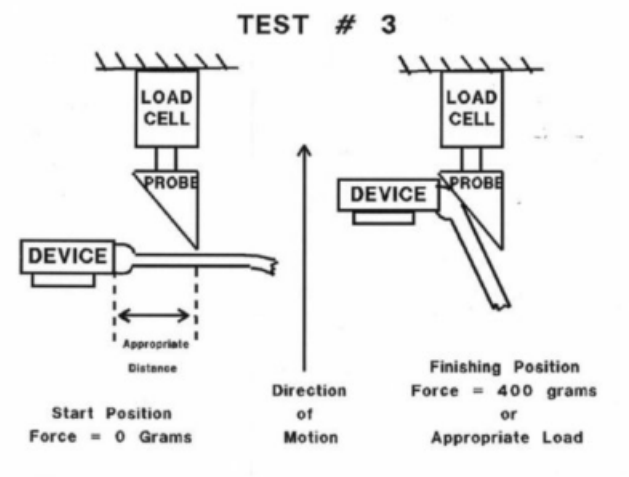


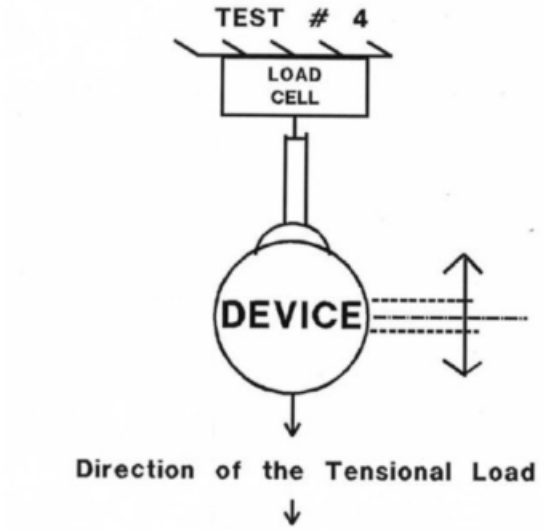
TEST # 1
Test 1(c) PERPENDICULAR TENSILE TEST
Illustrated Using Two Different Designs for
Bringing the Lead Out of the Body of the Device



TEST # 2







© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Annex K
(informative)

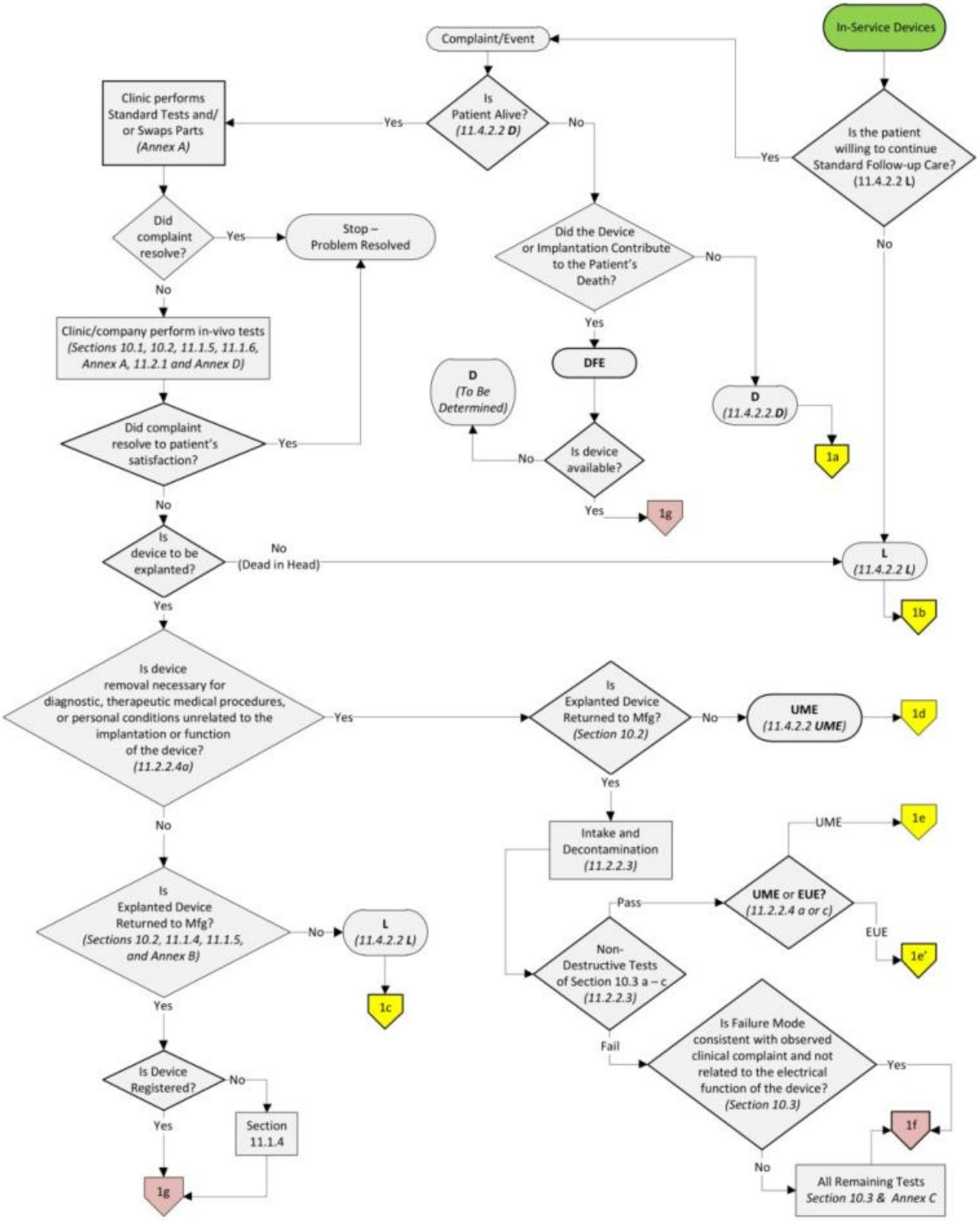
Logic flow diagram of the relationships between the required testing, explant category classification, and reliability reporting to both regulatory bodies and the public

This informative Annex provides a summary logic flow diagram of the relationships between the required testing, explant category classification, and reliability reporting to both regulatory bodies and the public, as described in Sections 10 and 11. The flow diagram extends across five pages and includes graphical links across pages to show continuity of the logical process.

The general content of the five pages is as follows:

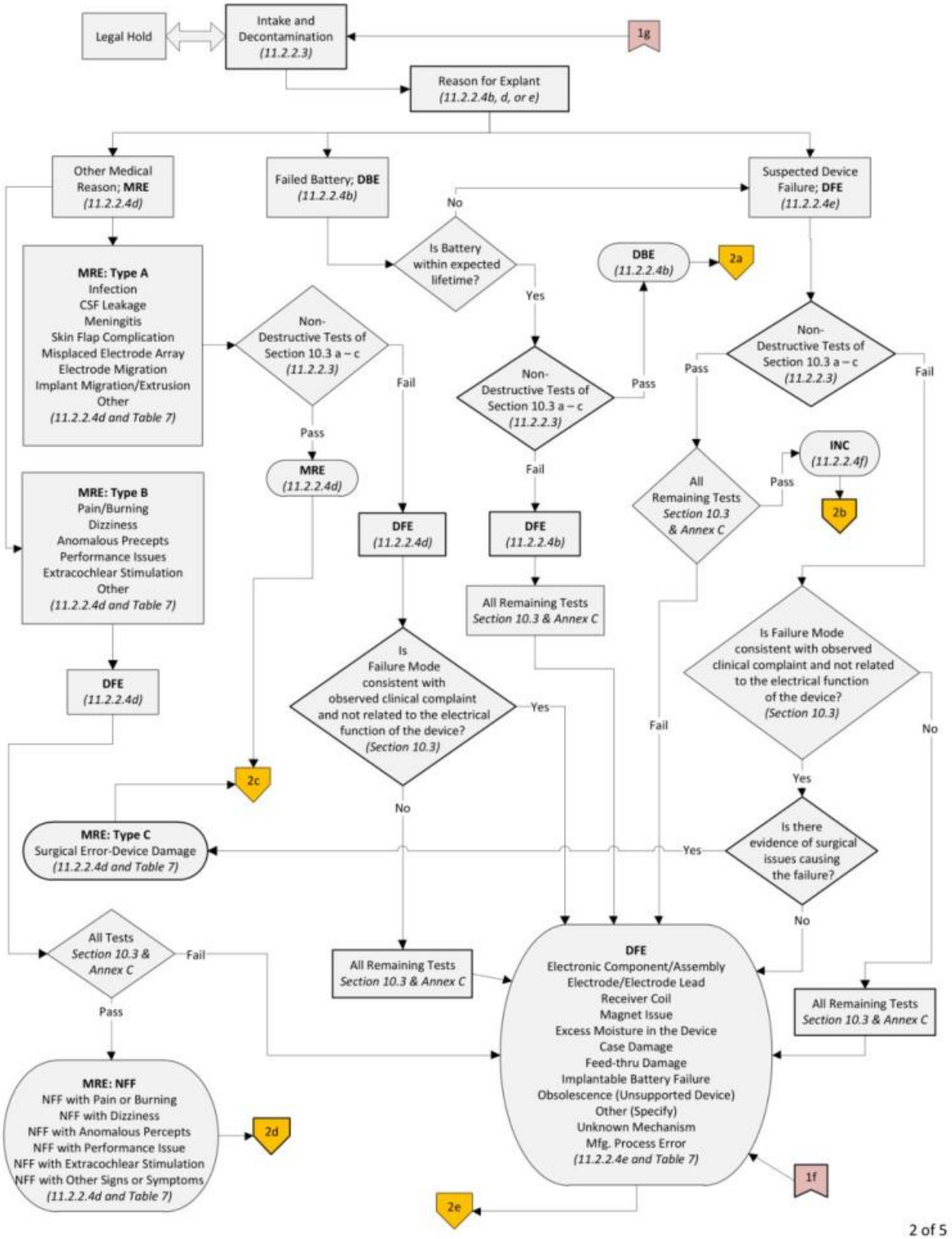
- Pages 1-of-5 and 2-of-5 describe the minimum procedures for failure analysis of each explanted, implantable component, as required by Sections 10.1, 10.3 and 11. The process is generally described in Figure 9 of Section 11.2.2.2, and the basis for classifying explants is summarized in Table 7 of Section 11.2.2.4.

- Pages 3-of-5 through 5-of-5 generally describe the analysis of the cumulative failure percentage of explanted devices and the reporting of such information to both regulatory bodies and the public, as described principally in Sections 10.2, 11.4.2.2, 11.4.2.3, and 11.5.

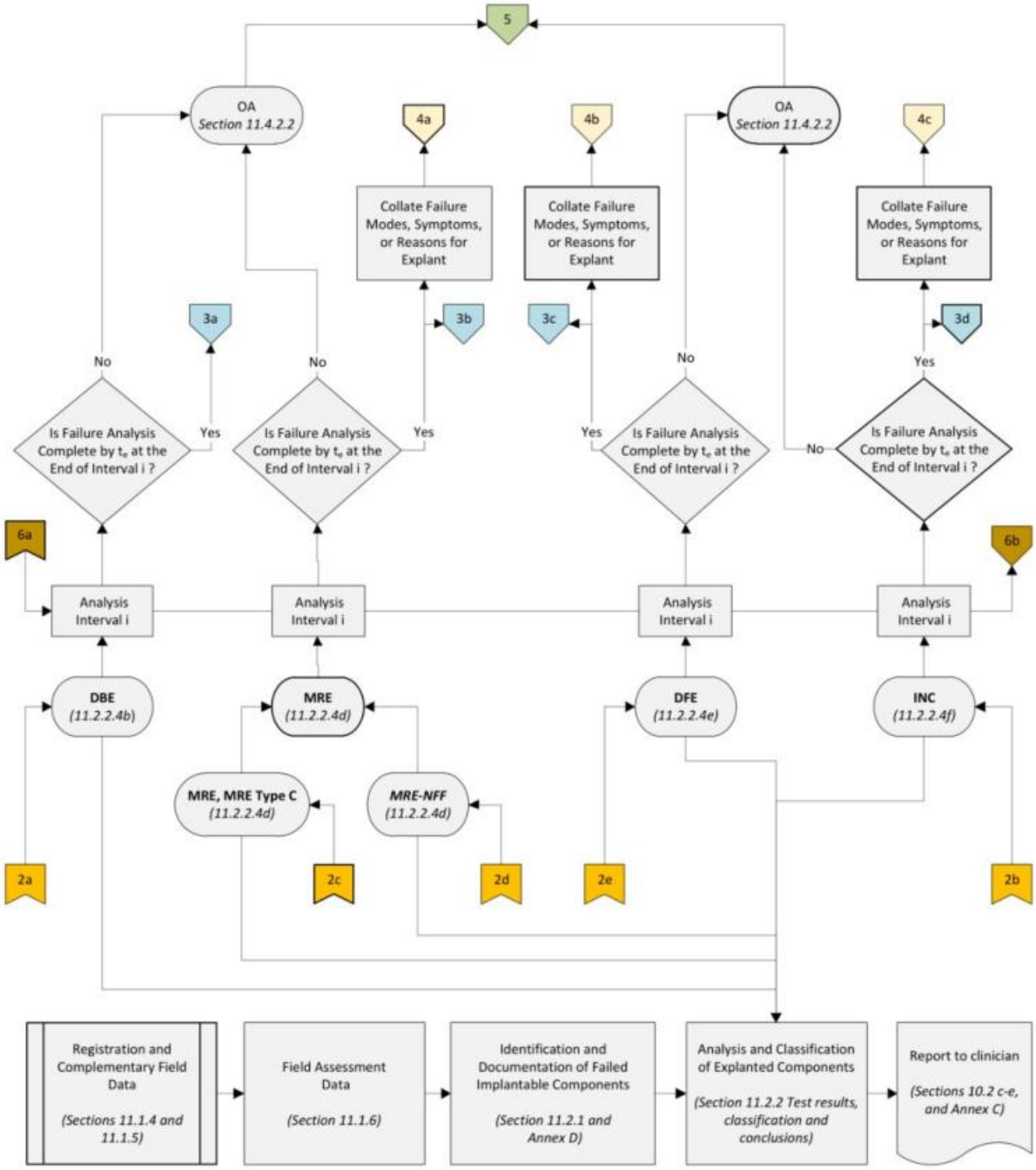


1 of 5

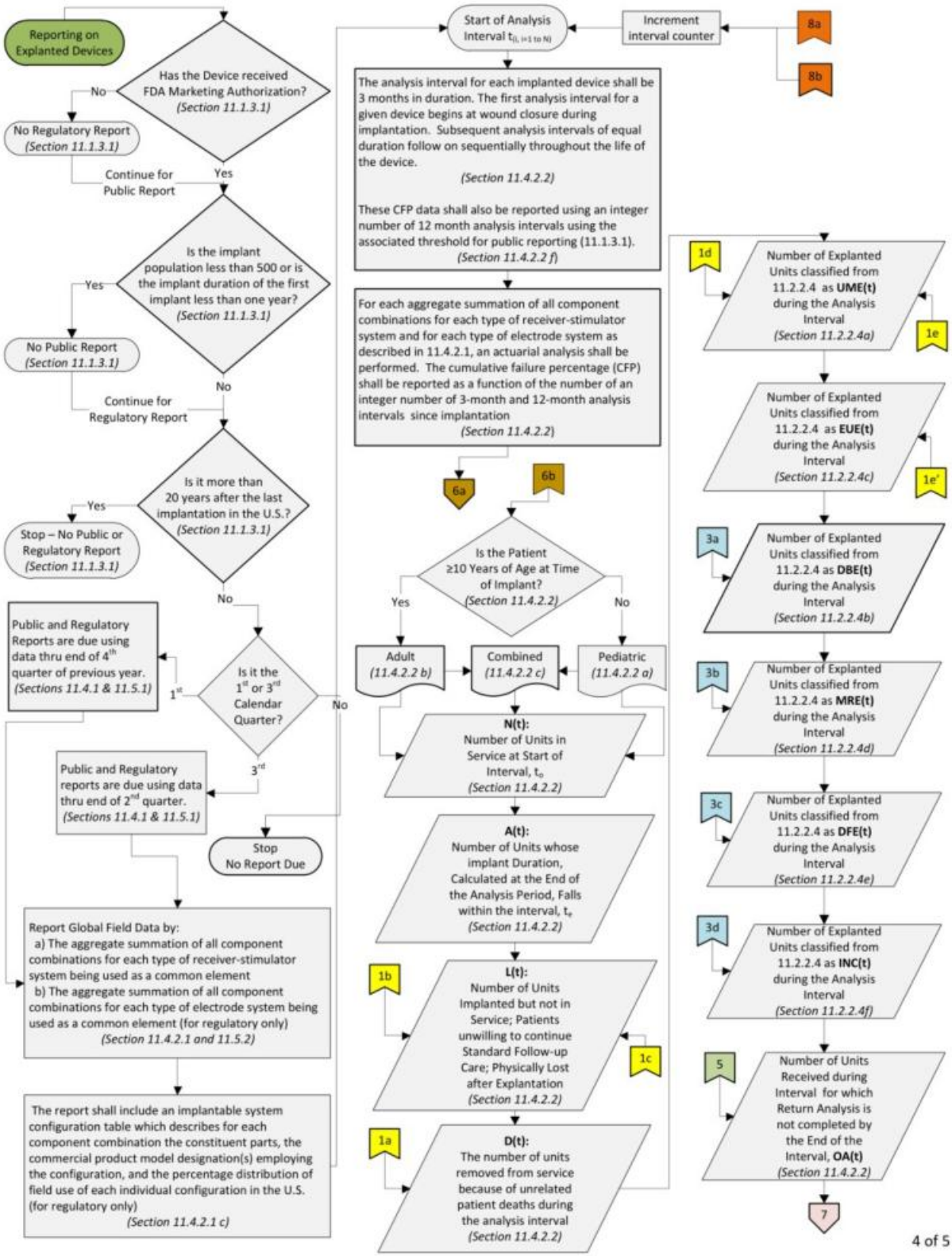
© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017


Legal Hold
Intake and Decontamination (11.2.2.3)
1g
Reason for Explant (11.2.2.4b, d, or e)
Other Medical Reason; MRE (11.2.2.4d)
Failed Battery; DBE (11.2.2.4b)
Suspected Device Failure; DFE (11.2.2.4e)
No
Is Battery within expected lifetime?
Yes
DBE (11.2.2.4b)
2a
MRE: Type A
Infection
CSF Leakage
Meningitis
Skin Flap Complication
Misplaced Electrode Array
Electrode Migration
Implant Migration/Extrusion
Other
(11.2.2.4d and Table 7)
Non-Destructive Tests of Section 10.3 a – c (11.2.2.3)
Fail
Pass
MRE (11.2.2.4d)
Non-Destructive Tests of Section 10.3 a – c (11.2.2.3)
Pass
Fail
Non-Destructive Tests of Section 10.3 a – c (11.2.2.3)
Pass
Fail
INC (11.2.2.4f)
2b
All Remaining Tests Section 10.3 & Annex C
Pass
MRE: Type B
Pain/Burning
Dizziness
Anomalous Precepts
Performance Issues
Extracochlear Stimulation
Other
(11.2.2.4d and Table 7)
DFE (11.2.2.4d)
DFE (11.2.2.4b)
All Remaining Tests Section 10.3 & Annex C
Is Failure Mode consistent with observed clinical complaint and not related to the electrical function of the device? (Section 10.3)
Yes
Fail
No
Is Failure Mode consistent with observed clinical complaint and not related to the electrical function of the device? (Section 10.3)
No
Yes
2c
MRE: Type C
Surgical Error-Device Damage
(11.2.2.4d and Table 7)
Yes
Is there evidence of surgical issues causing the failure?
No
All Tests Section 10.3 & Annex C
Fail
Pass
All Remaining Tests Section 10.3 & Annex C
DFE
Electronic Component/Assembly
Electrode/Electrode Lead
Receiver Coil
Magnet Issue
Excess Moisture in the Device
Case Damage
Feed-thru Damage
Implantable Battery Failure
Obsolescence (Unsupported Device)
Other (Specify)
Unknown Mechanism
Mfg. Process Error
(11.2.2.4e and Table 7)
All Remaining Tests Section 10.3 & Annex C
MRE: NFF
NFF with Pain or Burning
NFF with Dizziness
NFF with Anomalous Percepts
NFF with Performance Issue
NFF with Extracochlear Stimulation
NFF with Other Signs or Symptoms
(11.2.2.4d and Table 7)
2d
1f
2e

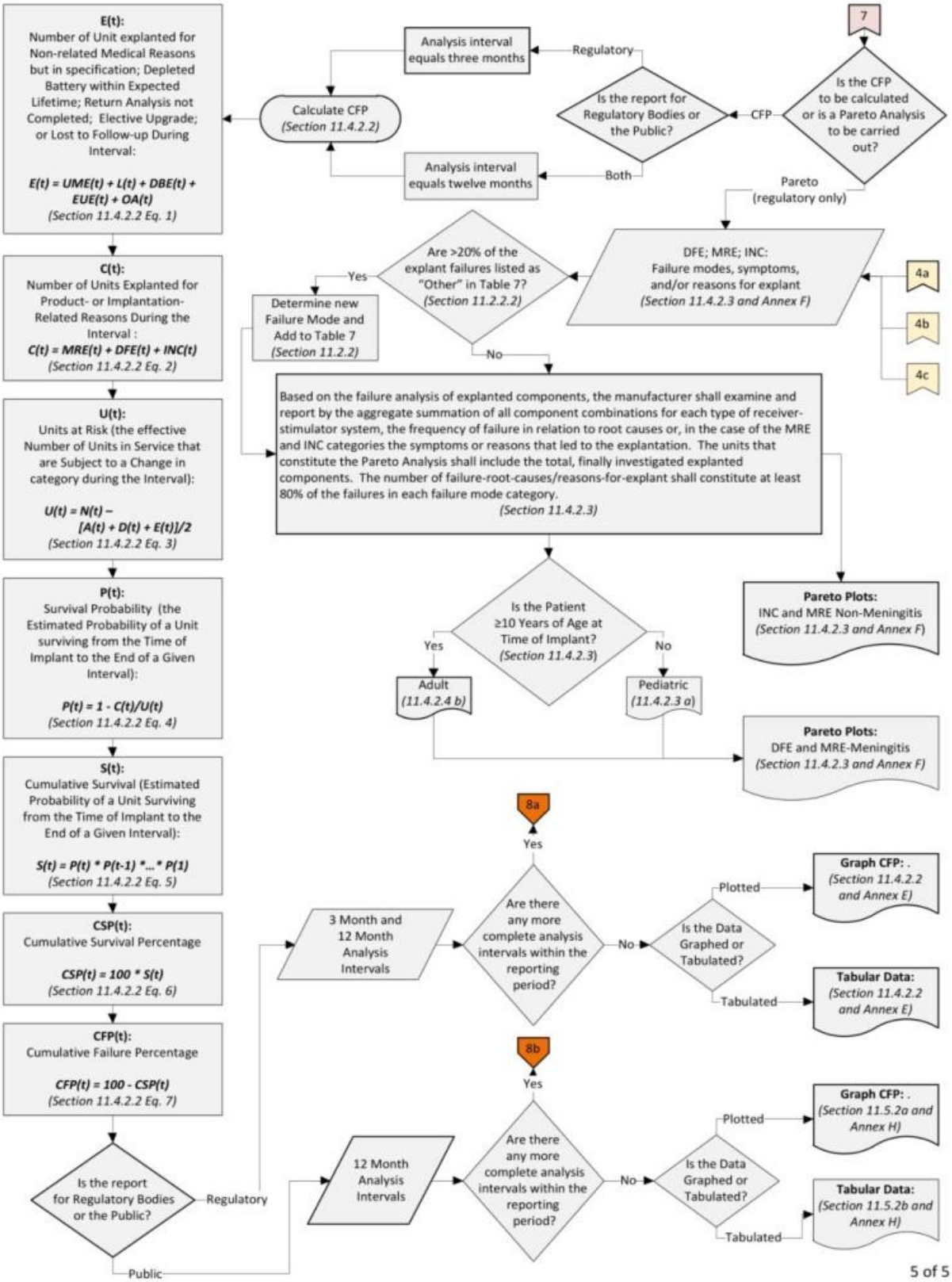
2 of 5



 © 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017


Reporting on Explanted Devices
Has the Device received FDA Marketing Authorization? (Section 11.1.3.1)
No
No Regulatory Report (Section 11.1.3.1)
Continue for Public Report
Yes
Is the implant population less than 500 or is the implant duration of the first implant less than one year? (Section 11.1.3.1)
Yes
No Public Report (Section 11.1.3.1)
Continue for Regulatory Report
No
Is it more than 20 years after the last implantation in the U.S.? (Section 11.1.3.1)
Yes
Stop – No Public or Regulatory Report (Section 11.1.3.1)
No
Public and Regulatory Reports are due using data thru end of 4th quarter of previous year. (Sections 11.4.1 & 11.5.1)
Is it the 1st or 3rd Calendar Quarter?
1st
3rd
No
Public and Regulatory reports are due using data thru end of 2nd quarter. (Sections 11.4.1 & 11.5.1)
Stop No Report Due
Report Global Field Data by:
a) The aggregate summation of all component combinations for each type of receiver-stimulator system being used as a common element
b) The aggregate summation of all component combinations for each type of electrode system being used as a common element (for regulatory only)
(Section 11.4.2.1 and 11.5.2)
The report shall include an implantable system configuration table which describes for each component combination the constituent parts, the commercial product model designation(s) employing the configuration, and the percentage distribution of field use of each individual configuration in the U.S. (for regulatory only)
(Section 11.4.2.1 c)
Start of Analysis Interval $t_{(i,\ i=1\ to\ N)}$
Increment interval counter
8a
8b
The analysis interval for each implanted device shall be 3 months in duration. The first analysis interval for a given device begins at wound closure during implantation. Subsequent analysis intervals of equal duration follow on sequentially throughout the life of the device.
(Section 11.4.2.2)
These CFP data shall also be reported using an integer number of 12 month analysis intervals using the associated threshold for public reporting (11.1.3.1).
(Section 11.4.2.2 f)
For each aggregate summation of all component combinations for each type of receiver-stimulator system and for each type of electrode system as described in 11.4.2.1, an actuarial analysis shall be performed. The cumulative failure percentage (CFP) shall be reported as a function of the number of an integer number of 3-month and 12-month analysis intervals since implantation
(Section 11.4.2.2)
6a
6b
Is the Patient ≥10 Years of Age at Time of Implant? (Section 11.4.2.2)
Yes
No
Adult (11.4.2.2 b)
Combined (11.4.2.2 c)
Pediatric (11.4.2.2 a)
N(t): Number of Units in Service at Start of Interval, t_o (Section 11.4.2.2)
A(t): Number of Units whose implant Duration, Calculated at the End of the Analysis Period, Falls within the interval, t_e (Section 11.4.2.2)
1b
L(t): Number of Units Implanted but not in Service; Patients unwilling to continue Standard Follow-up Care; Physically Lost after Explantation (Section 11.4.2.2)
1c
1a
D(t): The number of units removed from service because of unrelated patient deaths during the analysis interval (Section 11.4.2.2)
1d
Number of Explanted Units classified from 11.2.2.4 as UME(t) during the Analysis Interval (Section 11.2.2.4a)
1e
Number of Explanted Units classified from 11.2.2.4 as EUE(t) during the Analysis Interval (Section 11.2.2.4c)
1e'
3a
Number of Explanted Units classified from 11.2.2.4 as DBE(t) during the Analysis Interval (Section 11.2.2.4b)
3b
Number of Explanted Units classified from 11.2.2.4 as MRE(t) during the Analysis Interval (Section 11.2.2.4d)
3c
Number of Explanted Units classified from 11.2.2.4 as DFE(t) during the Analysis Interval (Section 11.2.2.4e)
3d
Number of Explanted Units classified from 11.2.2.4 as INC(t) during the Analysis Interval (Section 11.2.2.4f)
5
Number of Units Received during Interval for which Return Analysis is not completed by the End of the Interval, OA(t) (Section 11.4.2.2)
7

4 of 5



5 of 5

© 2017 Association for the Advancement of Medical Instrumentation ■ AAMI CI86:2017

Bibliography

ISO 5841-2:2014, *Implants for surgery—Cardiac pacemakers—Part 2: Reporting of clinical performance of populations of pulse generators or leads*

ISO 9000:2015, *Quality management systems—Fundamentals and vocabulary*

ISO 14708-3:2017, *Implants for surgery -- Active implantable medical devices -- Part 3: Implantable neurostimulators*

ISO 14937:2009, *Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

IEC 61649:2008. *Weibull analysis. Geneva: International Electrotechnical Commission, 2008.*

ISO/IEC Guide 51:2014, *Safety aspects—Guidelines for their inclusion in stand*ards

IEC 60300-1:2014, *Dependability management—Part 1: Dependability management systems*

IEC 61649:2008, *Weibull analysis*

United Nations. *Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria,* 5th revised edition, ST/SG/AC.10/11/Rev.5, 2009

Agnew WF, McCreery DB, Yuen TGH and Bullara LA. Local anaesthetic block protects against electrically-induced damage in peripheral nerve. *J Biomed Eng,* 12:301–308, 1990.

Agnew WF, McCreery DB, Yuen TGH and Bullara LA. MK-801 protects against neuronal injury induced by electrical stimulation. *Neuroscience*, 52(1):45–53, 1993.

Agnew WF, Yuen TG, Pudenz RH and Bullara LA. Neuropathological effects of intracerebral platinum salt injections. *J Neuropathol Exp Neurol,* 36(3):533-46, 1977.

An YH, Song SJ, Yoon SW, Kim JH, and Shim HJ. Cochlear implantation for total deafness after ipsilateral ventriculoperitoneal shunt surgery: technical report. *Acta Neurochir (Wien)*, 153(12):2479–83, 2011.

Barbier T, Piumatti R, Hecker B, Odille F, Felblinger J and Pasquier C. An RF-induced voltage sensor for investigating pacemaker safety in MRI. *MAGMA - Magnetic Resonance Materials in Physics, Biology and Medicine,* 27(6):539–549, 2014.

Battmer RD, Backous DD, Balkany TJ, Briggs RJS, Gantz BJ, van Hasselt A, Kim CS, Kubo T, Lenarz T, Pillsbury III HC and O'Donoghue GM. International classification of reliability for implanted cochlear implant receiver stimulators. *Otol Neurotol*, 31(8):1190–1193, 2010.

Baumann R, Lesinski-Schiedat A., Goldring JE, Gnadeberg D, Rittmann KL, Battmer RD, Karstens J and Lenarz T. The influence of ionizing radiation on the CLARION 1.2 cochlear implant during radiation therapy. *Am J Otol*, 20(1):50–52, 1999.

Biegler T, Rand BJT and Woods R. Limiting oxygen coverage on platinized platinum; Relevance to determination of real platinum area by hydrogen adsorption. *J Electroanal Chem*, 29(2):269–278, 1971.

Brummer SB and Turner MJ. Electrical stimulation with Pt Electrodes. II. Estimation of maximum surface redox (theoretical non-gassing) limits. *IEEE Trans Biomed Eng*, BME-24(5):440–443, 1977.

Clark GM, Clark J, Cardamone T, Clarke M, Nielsen P, Jones R, Arhatari B, Birbilis N, Curtain R, Xu J, Wagstaff S, Gibson P, O'Leary S and Furness J. Biomedical studies on temporal bones of the first multi-channel cochlear implant patient at the University of Melbourne. *Cochlear Implants Int.*, 15 Suppl 2:S1–15, 2014.

Dahm M, Shepherd RK and Clark GM. Topic: Reports in literature indicate that pediatric patients will be subject to an increase of skull growth of 12 mm (standard deviation of 5 mm) from the round window to the sino-dural angle. *Archives Otolaryngol Stockholm*, 1993.

Dewhirst MW, Viglianti BL, Lora-Michiels M, Hanson M and Hoopes PJ. Basic principles of thermal dosimetry and thermal thresholds for tissue damage from hyperthermia. *Int J Hyperthermia,* 19(3):267–294, 2003.

Gossman MS, Treaba CG and Kirk JR. Radiation therapy in cochlear implant recipients. *Otol Neurotol*, 32(4):553–557, 2011.

Greenwood, M. The natural duration of cancer. *Reports on Public Health and Medical Subjects* (London: Her Majesty's Stationery Office), 33:1–26, 1926.

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.

Klenzner T, Knapp F, Roehner F, von Wallenberg E, Mauch H, Pedersen P, Aschendorff A, Laszig R and Lutterbach J. Influence of ionizing radiation on Nucleus 24 cochlear implants. *Otol Neurotol*, 26(4):661–667, 2005.

Kumsa D, Hudak EM, Montague FW, Kelley SC, Untereker DF, Hahn BP, Condit C, Cholette M, Lee H, Bardot D and Takmakov P. Electrical neurostimulation with imbalanced waveform mitigates dissolution of platinum electrodes. *J Neural Eng*, 13(5):054001, 2016.

Leung RT, Shivdasani MN, Nayagam DA and Shepherd RK. In vivo and in vitro comparison of the charge injection capacity of platinum macroelectrodes. *IEEE Trans Biomed Eng,* 62(3):849–57, 2015.

Loizou PC. Mimicking the human ear. *IEEE Signal Processing Magazine*, Sept 1998, pp 101-130.

Loizou PC. Speech processing in vocoder-centric cochlear implants. In: Møller A, ed. *Cochlear and Brainstem Implants.* Basel, Karger. *Adv Otorhinolaryngol*, 64:109–143, 2006.

McCreery, DB, Agnew, WF, Yuen, TGH and Bullara, LA. Charge density and charge per phase as cofactors in neural injury induced by electrical stimulation. *IEEE Trans Biomed Eng*, 37(10):996–1001, 1990.

Merrill DR, Bikson M and Jefferys JGR. Electrical stimulation of excitable tissue: Design of efficacious and safe protocols. Invited Review. *J Neurosci Methods*, 141:171–198, 2005.

Mortimer JT, Kaufman D and Roessman U. Intramuscular electrical stimulation: tissue damage. *Ann Biomed Eng,* 8(3):235–44, 1980.

Morton, SL, Daroux, ML and Mortimer, JT. The role of oxygen reduction in electrical stimulation of neural tissue. *J Electrochem Soc*, 141:122–130, 1994.

Nadol JB Jr, O'Malley JT, Burgess BJ and Galler D. Cellular immunologic responses to cochlear implantation in the human. *Hear Res*, 318:11–17, 2014.

Olney JW, deGubareff T and Sloviter RS. "Epileptic" brain damage in rats induced by sustained electrical stimulation of the perforant path. II. Ultrastructural analysis of acute hippocampal pathology. *Brain Res Bull,* 10(5):699–712, 1983.

Raicevich G, Burwood E and Dillon H. Taking the pressure off bone conduction hearing aid users. *Australian and New Zealand J Audiology,* 30(2):113–118, 2008.

Ralston A, Stevens G, Mahomudally E, Ibrahim I and Leckie E. Cochlear implants: response to therapeutic irradiation. *Int J Radiat Oncol Biol Phys*, 44(1):227–231, 1999.

Robblee LS, McHardy J, Marston JM and Brummer SB. Electrical stimulation with Pt electrodes. V. The effect of protein on Pt dissolution. *Biomaterials*, 1(3):135–139, 1980.

Robblee LS, McHardy J, Agnew WF and Bullara LA. Electrical stimulation with Pt electrodes. VII. Dissolution of Pt electrodes during electrical stimulation of the cat cerebral cortex. *J Neurosci Methods*, 9(4):301–308, 1983.

Rose TL and Robblee LS. Electrical stimulation with Pt electrodes. VIII. Electrochemically safe charge injection limits with 0.2 us pulses. *IEEE Trans Biomed Eng*, 37(11):1118–1120, 1990.

Rubin LG, Papsin B, and Committee on Infectious Diseases and Section on Otolaryngology-Head and Neck Surgery. Cochlear implants in children: surgical site infections and prevention and treatment of acute otitis media and meningitis. *Pediatrics* 126:381–391, 2010.

Shannon RV. A model of safe levels for electrical stimulation. *IEEE Trans Biomed Eng*, 39(4):424–426, 1992.

Shepherd RK, Linahan N, Xu J, Clark GM and Araki S. Chronic electrical stimulation of the auditory nerve using non-charge-balanced stimuli. *Acta Otolaryngol*, 119:674–684, 1999.

U.S. Food and Drug Administration. Benefits and Risks of Cochlear Implants. June 6, 2014. Available at: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/CochlearImplants/ucm062843.htm.

Wiet RM and El-Kashlan HK. Cochlear implantation in the presence of a programmable ventriculoperitoneal shunt, *Otol Neurotol*, 30:704–707, 2009.

Zwolan TA, O`Sullivan MB, Fink NE, Niparko JK, and CDACI Investigative Team. Electric charge requirements of pediatric cochlear implant recipients enrolled in the Childhood Development after Cochlear Implantation study. *Otol Neurotol,* 29:143-148, 2008.