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 need 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.

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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).

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Glossary of equivalent standards

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

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation
Cochlear Implant Committee

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

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

Co-Chairs:
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Julie Verhoff, AuD, PhD

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

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.

