



June 2, 2015

Dear ACI Alliance Member,

We would like to make you aware of an important document that, as a professional working with cochlear implants, you should be familiar with and have input on. *Cochlear Implant Systems – Safety, Performance and Reliability*, available at the link below, is a voluntary standard for cochlear implants that is available for public review and comment for a limited time period. The standard development process was coordinated by the Association for the Advancement of Medical Instrumentation (AAMI).

https://standards.aami.org/kws/public/document?document_id=6252&wg_abbrev=PUBLIC_REV

This standard reflects the collective effort of a committee of healthcare professionals, representatives of cochlear implant device manufacturers, and staff of the U.S. Food and Drug Administration (FDA). The purpose of this document is to provide a voluntary standard for “the information that should be provided with or on the (cochlear implant) product, basic safety and performance criteria that should be considered when qualifying the device for clinical use, and 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”.

We realize that reviewing the entire document may be a daunting task. Therefore, we are providing an index that highlights and summarizes the sections we think will be particularly valuable for hearing health care professionals to review. We recommend that you review this index, select the topics you are most interested in, and provide comments to AAMI regarding the sections of the standard you have reviewed. Please submit your comments in writing **by July 20, 2015** using the comment template:

https://standards.aami.org/kws/public/document?document_id=5852&wg_abbrev=PUBLIC_REV

Send comments to the project manager: Colleen Elliott via email to: celliot@aami.org

If you do not wish to submit formal comments but would like to share your insights for inclusion in our ACI Alliance organizational comments, you may send your ideas to our Executive Director Donna Sorkin at dsorkin@acialliance.org.

Thank you for considering this important task.

Sincerely,

American Cochlear Implant Alliance

Future AAMI CI86, 21-May-15 Preliminary Final Draft Rev. 2
Cochlear Implant Systems – Safety, Performance and Reliability

Overview to Facilitate Review by Hearing Healthcare Professionals

1. Scope

- Overview of the standard

5. General requirements for characterizing a cochlear implant system

- Components of cochlear implant systems that are addressed in the standard

6. General requirements for implantable parts

- Requirements for issues such as biocompatibility and electromagnetic capabilities

7. General requirements for non-implantable parts

- Requirements for issues such as biocompatibility, external battery safety, electromagnetic compatibility, programming software requirements, and user accessories and clinical tools

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

- Procedures that should be followed when devices are evaluated in vivo and also discusses protocols that manufacturers and clinicians should follow when removal of a device is warranted. This section also provides information regarding manufacturer analysis of a device following explant

11. Reliability monitoring and reporting

- Describes the procedures, record-keeping, analyses, and documents required for manufacturers to report device reliability of both internal and external components. This includes classification of reasons for internal device explant as 1) Medical, 2) Device Failure (out of spec), or 3) No Fault Found. Reliability of non-implantable components will also be tracked and reported along with their reason for failure
- Describes the procedure that will be used to calculate Cumulative Failure Percentage – an actuarial analysis that will indicate the percentage of devices that have failed for various reasons as a function of the number of years since implantation
- Describes requirements for reporting field reliability data to the public and the clinical community

12. Information on use, warnings, and hazards

- Describes the documentation that manufacturers should provide regarding use, warnings, and hazards. Includes instructions on proper use of the device by the physician, audiologist, and/or patient

16. Safety of secondary features of the active implantable medical device

- Describes the prevention of magnetic field interference with other medical devices and prevention of harm caused by headpiece retention

19. Safety from heat sources

- Describes thermal limits on outer surfaces of implantable parts, external parts, external batteries, and interface equipment

21. Conditions for safe MRI usage

22. Requirements for immunity

- Describes immunity to and procedures for testing immunity to therapeutic ionizing radiation therapy, applied currents during surgery, and stresses during defibrillation

Key Items in Appendix

Annex A - Clinical identification and management of cochlear implant device failures

- Overview of the steps that clinicians should take during the implant process to help identify a potential device failure

Annex B - Clinical checklist prior to explantation

- Signs and symptoms checklist aimed at improving communication between clinicians and device manufacturers when a decision has been made to explant a device

Annex C - Returned implant analysis report template

- Template that manufacturers will use to report the analysis results for explanted devices

Annex D - Indications of performance decline

- Outline of common symptom categories that indicate performance decline

Annex E – Reliability reporting to regulatory bodies

- Outline of acceptable graphical presentations of implant reliability for regulatory bodies (not available to the public)

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

- Outline of graphical presentations of failed component return rate data for external device components

Annex H – Reliability reporting template for the public and clinical community

- Instructions for patients and their families regarding how to read a manufacturer’s reliability report and example reliability data as it will be made available to the public

Annex I - Product specification data sheets

- Sample specification sheets for implants, electrodes, sound processing strategy, sound processor, and remote control

Annex K – Topics for consideration in future standard revisions