ANSI/AAMI/ISO 14708-3: 2017
Implants for surgery — Active implantable medical devices — Part 3: Implantable neurostimulators
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.
Abstract: Specifies particular requirements for active implantable medical devices intended for electrical stimulation of the central or peripheral nervous system in order to provide basic assurance of safety for both patients and users. It amends and supplements ISO 14708-1:2014.

Keywords: implant, nerves, neurosurgery
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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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 at the address below, this list 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
Implantable Neurostimulators Working Group

The adoption of ISO 14708-3 as an American National Standard was initiated by the AAMI Implantable Neurostimulators Working Group (NS/WG 2). AAMI NS/WG 2 functions as a U.S. sub-Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from AAMI NS/WG 2 played a very active part in developing the ISO standard.

At the time this document was published, the AAMI Implantable Neurostimulators Working Group had the following members:

Cochairs: Daniel Aghassian, Boston Scientific

Members:
- Kristen Bowsher, FDA/CDRH
- Bryan Byerman, LivaNova PLC
- Warren Dabney, Micro Systems Engineering Inc
- Rob Egemo, St Jude Medical Inc
- Harry Friedman, Memphis Neurosurgery Clinic PC
- Barbara Gibb, NeuroPace Inc
- Jeff Johnson, University of Cincinnati
- Richard North, Sinai Hospital of Baltimore
- Eric Schepis, Halyard Health
- Curt Sponberg, Medtronic Inc Campus
- Bob Stevenson, Greatbatch Medical

Alternates: Amar Chanani, Halyard Health
- Hongying Cui, Medtronic Inc Campus
- John Doucet, FDA/CDRH
- Casey Haley, LivaNova PLC
- Ron Reitan, Boston Scientific Corporation

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.
Background of AAMI adoption of ISO 14708-3:2017

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee (TC) 150 Subcommittee (SC) 6, *Active implants*, to provide requirements for active implantable medical devices intended for electrical stimulation of the central or peripheral nervous system and to provide basic assurance of safety for both patients and users. This revision aligns the document with recent editions of ISO 14117:2012, ISO 14708-1:2014, IEC 60601-1-2:2014 and ISO/TS 10974.

U.S. participation in this ISO SC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 6, administered by the Association for the Advancement of Medical Instrumentation (AAMI).


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

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

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. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

NOTE—Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

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. 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—Beginning with the ISO foreword on page viii, this American National Standard is identical to ISO 14708-3:2017.
Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, Implants for surgery, SC 6, Active implants.

This second edition cancels and replaces the first edition (ISO 14708-3:2008), which has been technically revised.

A list of all parts in the ISO 14708 series can be found on the ISO website.
Introduction

This document specifies particular requirements for active implantable medical devices intended for electrical stimulation of the central or peripheral nervous system, to provide basic assurance of safety for both patients and users. It amends and supplements ISO 14708-1:2014, hereinafter referred to as ISO 14708-1.

The requirements of this document take priority over those of ISO 14708-1.

Devices that use electricity to stimulate the nervous system are commonly called “neurostimulators.” They produce controlled electrical pulses that are delivered through electrodes in contact with a specific target area. Whether or not a neurostimulator is totally or partially implantable, a lead or extension is usually required to convey stimulation pulses from a form of pulse generator to the electrodes, although newer forms of devices might not utilize leads or extensions. An external programmer might be used to adjust device parameters.

Currently, several types of neurostimulators exist for treating the central or peripheral nervous system. This document is intended to apply to these neurostimulator types regardless of therapy.

This document is relevant to all parts and accessories of implantable neurostimulators, including programmers, software, and technical manuals. Not all parts or accessories might be intended to be totally or partially implanted, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance intended by the manufacturer.

Not included in the scope of this document are non-implantable medical devices, such as external neurostimulators and RF-coupled neurostimulators, even though such devices might have implantable parts, because they are covered under the IEC 60601-1 series of standards.

Within this document, the following terms are used to amend and supplement ISO 14708-1:

“Replacement”: the clause of ISO 14708-1 is replaced completely by the text of this document.

“Addition”: the text of this document is additional to the requirements of ISO 14708-1.

“Amendment”: the clause of ISO 14708-1 is amended as indicated by the text of this document.

“Not used”: the clause of ISO 14708-1 is not applied in this document.

Subclauses, figures, or tables that are additional to those of ISO 14708-1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.
Implants for surgery — Active implantable medical devices — Part 3: Implantable neurostimulators

1 Scope

This document is applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES intended for electrical stimulation of the central or peripheral nervous system.

The tests that are specified in this document are type tests and are to be carried out on a sample of a device to assess device behavioural responses, and are not intended to be used for the routine testing of manufactured products.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14117:2012, Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices

ISO 14708-1:2014, Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

ISO 14971, Medical devices — Application of risk management to medical devices

ISO/TS 10974:—1, Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device


1 Under preparation.
3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

3.101 implantable neurostimulator
INS
active implantable medical device intended for electrical stimulation of the central or peripheral nervous system

Note 1 to entry: For the purposes of this document, an implantable neurostimulator can be a single article, 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 might be required to be partially or totally implanted, e.g. programmers.

3.102 implantable pulse generator
IPG
part of an implantable neurostimulator (3.101), consisting of a power source and electronic circuit, which produces a stimulation voltage or current pulse

3.103 MR Conditional
item with demonstrated safety in the MR environment within defined conditions

Note 1 to entry: Adapted from ASTM F2503, 3.1.11.

3.104 projected service life
period after implantation when the implantable neurostimulator (3.101) remains within stated specifications and characteristics

3.105 DUT
device under test
device being tested, including conductive leads

Note 1 to entry: Not all tests require conductive leads.

4 Symbols and abbreviated terms

This clause of ISO 14708-1 applies.

5 General requirements for active implantable medical devices

This clause of ISO 14708-1 applies, except as follows.

Additional subclause:

5.101 Wireless coexistence and wireless quality of service
When communication with the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE is provided through wireless communication channels, the MANUFACTURER shall evaluate wireless coexistence and wireless quality of service through the RISK MANAGEMENT PROCESS and apply the appropriate RISK CONTROL measures to protect the patient from HARM (see 28.105).

Compliance is checked by the inspection of the RISK MANAGEMENT FILE.

6 Requirements for particular ACTIVE IMPLANTABLE MEDICAL DEVICES

No additional requirements are specified in this clause.

7 General arrangement of the packaging

This clause of ISO 14708-1 applies.

8 General markings for ACTIVE IMPLANTABLE MEDICAL DEVICES

This clause of ISO 14708-1 applies.

9 Markings on the sales packaging

This clause of ISO 14708-1 applies.

10 Construction of the sales packaging

This clause of ISO 14708-1 applies.

11 Markings on the sterile pack

This clause of ISO 14708-1 applies.

12 Construction of the non-reusable pack

This clause of ISO 14708-1 applies.

13 Markings on the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

14 Protection from unintentional biological effects being caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.
15 Protection from harm to the patient or user caused by external physical features of the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

16 Protection from harm to the patient caused by electricity

This clause of ISO 14708-1 applies.

17 Protection from harm to the patient caused by heat

This clause of ISO 14708-1 applies except as follows.

17.1 Replacement:

In the absence of external influence, an implantable part of the INS, not intended to supply heat to the patient, shall comply with at least one of the following conditions (a, b, or c) when implanted, and when in normal operation, including recharge:

NOTE Examples of external influences include exposure to MRI, electrosurgery, external defibrillation, ultrasound, and electromagnetic fields.

a) no outer surface greater than 39 °C,

b) no tissue receives a thermal dose greater than the CEM43 dose thresholds in Table 101, or

c) manufacturer's evidence that a higher temperature rise, than indicated in Table 101, is justified for a particular application.

Because the values in Table 101 represent tissue dose thresholds, the manufacturer’s risk assessment shall include an analysis of any effects to the patient due to the time/temperature relationship.

<table>
<thead>
<tr>
<th>Tissue</th>
<th>CEM43 dose threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>muscle</td>
<td>40</td>
</tr>
<tr>
<td>fat</td>
<td>40</td>
</tr>
<tr>
<td>peripheral nerve</td>
<td>40</td>
</tr>
<tr>
<td>skin</td>
<td>21</td>
</tr>
<tr>
<td>bone</td>
<td>16</td>
</tr>
<tr>
<td>brain</td>
<td>2</td>
</tr>
<tr>
<td>BBB (blood brain barrier)</td>
<td>15</td>
</tr>
</tbody>
</table>

Table 101 — CEM43 dose thresholds for various tissues

The CEM43 value is calculated using Formula (1):

\[
CEM43 = \sum_{i=1}^{n} t_i \times R^{(43-T_i)}
\]

where

\( t_i \) is the \( i \)-th time interval in minutes;

NOTE Examples of external influences include exposure to MRI, electrosurgery, external defibrillation, ultrasound, and electromagnetic fields.
\[ T_i \] is the average temperature of the tissue in degrees Centigrade during the interval \( t_i \);
\[ R \] is 0.25 for \( T < 43 \, ^\circ C \) and 0.5 for \( T \geq 43 \, ^\circ C \);
\( n \) is the number of samples taken during the heating duration.

Formula (1) is valid for temperatures between 39 °C and 57 °C.

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

18 Protection from ionizing radiation released or emitted from the active implantable medical device

This clause of ISO 14708-1 applies.

19 Protection from unintended effects caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

20 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by external defibrillators

This clause of ISO 14708-1 applies except as follows.

20.1 Not used.

21 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by electrical fields applied directly to the patient

This clause of ISO 14708-1 applies.

22 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by miscellaneous medical treatments

22.1 Ultrasonic energy

This clause of ISO 14708-1 applies.

22.2 MRI

NOTE 1 This clause does not apply to devices that are not labelled MR CONDITIONAL.

Implantable parts of an INS and any non-implantable components and accessories, which are labelled MR CONDITIONAL, shall be designed and constructed so that no irreversible change to the device or unacceptable risk to the patient results from exposure to MRI.

Assessment: For an implantable part of an INS intended to be used in patients who undergo a magnetic resonance scan in 1.5 T, cylindrical bore, whole body MR scanners, the requirements of ISO/TS 10974 shall apply. For non-implantable components and accessories, or as an alternative for implantable parts, the manufacturer may demonstrate safety using similar or equivalent means.

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