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Implants for surgery — Active implantable medical devices —

Part 3: Implantable neurostimulators

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 3: Neurostimulateurs en implant

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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*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 61000-4-3:2006+A1:2007+A2:2010, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

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:

— IEC Electropedia: available at http://www.electropedia.org/

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

1) Under preparation.

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 101 — CEM43 dose thresholds for various tissues

Tissue	CEM43 dose threshold
muscle	40
fat	40
peripheral nerve	40
skin	21
bone	16
brain	2
BBB (blood brain barrier)	15

The CEM43 value is calculated using Formula (1):

$$\mathrm{CEM43} = \sum_{i=1}^{n} t_i \times R^{(43-T_i)} \quad (1)$$

where

t_i is the i-th time interval in minutes;

T_i is the average temperature of the tissue in degrees Centigrade during the interval t_i;

R is 0,25 for T <43 °C and 0,5 for $T \geq 43$ °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.

The outcome of each test shall not result in an unacceptable risk to the patient. Additional acceptance criteria are listed in Table 102.

If device samples are used for testing, they shall meet all manufacturer specifications after testing is completed.

Compliance is checked by inspection of test reports and the risk management file.

Table 102 — Acceptance criteria for test requirements of ISO/TS 10974

Test requirement	ISO/TS 10974 Clause #	Acceptance criteria to protect patient from harm
RF field-induced heating of the AIMD	8	RF-induced heating of adjacent tissue(s) shall not cause an unacceptable risk. This heating value shall be below a limit supported by scientific rationale linked to clinical significance for the adjacent tissue(s). The value used for assessment could be CEM43, applied RF power, temperature, or any other measurable and relevant parameter. If temperature rise is ≤2 °C, then no further scientific rationale is needed.
Gradient field-induced device heating	9	Gradient induced heating of adjacent tissue(s) shall not cause an unacceptable risk. This heating value shall be below a limit supported by scientific rationale linked to clinical significance for the adjacent tissue(s). The value used for assessment could be CEM43, applied RF power, temperature, or any other measurable and relevant parameter. If temperature rise is ≤2 °C, then no further scientific rationale is needed.
Gradient field-induced vibration	10	Gradient induced vibration shall not cause an unacceptable risk.
B_0-induced force	11	Magnetically induced force shall be less than the weight of the device or less than a greater specified value that is supported by a scientific-based rationale that the force of this specified value shall not cause an unacceptable risk.
B_0-induced torque	12	Magnetically 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 scientific-based rationale that the force of this specified value shall not cause an unacceptable risk.
Gradient field-induced lead voltage	13	Induced lead voltages shall not cause an unacceptable risk.
B_0 field-induced device malfunction	14	Device malfunction shall not cause an unacceptable risk.
RF field-induced device malfunction	15	Device malfunction shall not cause an unacceptable risk.
Gradient field-induced device malfunction	16	Device malfunction shall not cause an unacceptable risk.
Combined fields	17	The combined fields test outcome shall not result in an unacceptable risk.

23 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces

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

23.1

Amendment:

Following the test, the non-implantable part of the active implantable medical device shall operate as specified in IEC 60601-1.

24 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by electrostatic discharge

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

24.1

Replacement:

The requirements of IEC 60601-1-2 shall apply to the non-implantable parts.

NOTE While the electrostatic discharge is applied only to the non-implantable parts, operation of the ACTIVE IMPLANTABLE MEDICAL DEVICE is evaluated as a system following the test.

Compliance is checked as specified in IEC 60601-1-2.

25 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by atmospheric pressure changes

This clause of ISO 14708-1 applies.

26 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by temperature changes

This clause of ISO 14708-1 applies.

27 Protection of the active implantable medical device from electromagnetic non-ionizing radiation

Replacement:

27.101 General

Implantable parts of the implantable neurostimulator (INS) are expected to maintain their intended use and shall not result in an unacceptable risk because of susceptibility to electrical influences due to external electromagnetic fields.

Assessment: The tests of this clause shall be used to assess device behavioural responses when exposed to electromagnetic (EM) fields representing the general public environment.

NOTE The tests in this clause apply only to the implantable parts. Non-implantable parts are covered by IEC 60601-1-2 (see ISO 14708-1:2014, 5.1).

Compliance is checked by review of the risk management file and test reports.

27.102 Test conditions

27.102.1 Acceptance criteria

During testing of all clauses, the acceptance criteria (pass/fail criteria) shall be based on the manufacturer's intended use of the INS and on a risk assessment, as follows:

— it is expected that the performance intended by the manufacturer will be maintained, and

— no hazardous situations occur that could lead to an unacceptable risk.

Prior to testing, risks shall be identified, taking into account the reasonably foreseeable electromagnetic (EM) environment that is likely to occur during its intended use. Immunity test levels in Clause 27 are based on the reasonably foreseeable maximum levels found in the general public EM environment. Each risk shall be evaluated through a design analysis that takes account of any risk control, according to ISO 14708-1:2014, 5.5.4.

The risk assessment process, performed in accordance with ISO 14971, could result in hazardous situations being identified (see ISO 14971:2007, Figure E.1). Since actual risk cannot be observed

during testing, it will be necessary to observe the performance of the device to see if any hazardous situations occur.

Pass/fail criteria shall be defined prior to testing. Ideally, these criteria can be measurable or observable during testing. If not, the manufacturer shall specify an alternative method for determining that the DUT met the required pass/fail criteria during the test. The use of special hardware or software might be necessary.

If the pass/fail acceptance criteria are not met during and after testing, the manufacturer shall substantiate DUT behavioural responses and explain why the overall risk(s) are acceptable (see Table 103). In no cases are irreversible changes in performance, outside of specification, allowed.

27.102.2 Test configuration and setup

The INS shall be tested in representative configurations, consistent with intended use, that are likely to be the most susceptible to EM disturbances. This shall be determined using risk analysis, experience, engineering analysis, or pretesting.

Unless specified otherwise in a particular test, the test setup shall include

— the IPG,

— attachment of patient leads to all ports as necessary to achieve the intended use,

— for devices that have more than one available electrode configuration for stimulation, such as bipolar or unipolar, they shall be tested with the electrode configuration that is the most susceptible to electromagnetic disturbances, provided that the circuit design and components are equivalent, and

— termination of the implantable parts of the INS as necessary to simulate normal impedance of the patient.

For all tests, provision shall be made to determine the device's behavioural responses, preferably during testing. If the operation of the DUT cannot be observed or verified during the test, the manufacturer shall specify an alternative method for determining that the DUT met the required pass/fail criteria during the test. The use of special hardware or software might be necessary.

27.102.3 Operating functions, modes, and settings

The INS shall be tested using the functions, modes, and settings, consistent with intended use, that are likely to be the most susceptible to EM disturbances. This shall be determined using risk analysis, experience, engineering analysis, or pretesting.

Except for the requirements of 5.101, if the intended use includes a wireless communication channel, the wireless communication function shall be evaluated and tested for EMC in accordance with IEC 60601-1-2.

NOTE A wireless communication function does not have to be tested twice for EMC, as it would be if it were tested according to this document and IEC 60601-1-2.

27.102.4 Patient physiological simulation

If simulation of the patient is required to verify normal operation of the INS, it shall be provided during immunity testing. Physiological simulation shall not provide an intentional conductive or capacitive connection to earth other than that required by 27.102.2.

27.103 Risk management and test report documentation

The information listed in Table 103 shall be provided by the manufacturer.

Table 103 — Minimum risk management and test report contents

No.	Item
1	Description of the intended use, and any unacceptable risks and associated hazardous situations, resulting from the risk assessment.
2	Pass/fail criteria: how it was determined.
3	Pass/fail criteria: how it was monitored during testing.
4	Effects on the DUT that were observed during or after the application of the test disturbances, and the duration for which these effects persisted.
5	If the intended use is not maintained during testing, or if a hazardous situation occurs, the manufacturer shall substantiate DUT behavioural responses and explain why they are not unacceptable.
6	Applicability/tests not performed. The decision and justification not to perform a measurement or test shall be documented. Deviations and modifications to tests shall also be described.
7	DUT configuration during the test, including a block diagram of DUT configuration and all peripherals and auxiliary equipment used.
8	DUT functions, settings, and operating modes listed by test.
9	Name and location of the test facility.
10	Names and functions or equivalent identification of the persons authorizing the test report.
11	Description of the DUT. For example, the device name, model number, manufacturer, and serial numbers, or other means of identification.
12	DUT software/firmware version.
13	Prototype or production version of the DUT. For prototypes, describe the relationship to production versions.
14	Compliance summary statement. Compliance of the DUT with each test.
15	Test data that support the compliance determination for each test performed.
16	Simulators, accessories and auxiliary equipment, including patient physiological and simulation.
17	Documentation of any special hardware or software needed to perform the tests.
18	Test equipment used, including calibration or maintenance dates.
19	Dwell time for each immunity test requiring a dwell time.
20	DUT modifications needed in order to pass any of the tests. A statement that they will all be incorporated into production units.
21	Photographs of each test setup including DUT and all peripherals and auxiliary equipment used.

27.104 Protection from static magnetic fields of flux density up to 50 mT

NOTE If the requirements of the B_0 field-induced device malfunction test of 22.2 have been met, then this test is not required. However, this test is not a substitute for any test in 22.2.

For this test, leads are not required and electrode configuration is not applicable.

Test equipment: A field coil capable of generating a magnetic field with a flux density of at least 50 mT in the region to be occupied by the DUT.

Test procedure: The required magnetic field flux density shall be generated before placing the DUT in the field. Then the DUT shall be placed into the centre of the test coil. After at least 15 s of exposure to the magnetic field, the DUT shall be removed from the field. Reorient the DUT so that a second orthogonal axis is aligned with the axis of the field coil, and again subject the DUT to the required field. Repeat with the third orthogonal axis aligned with the axis of the field coil.

Evaluation of test results: The DUT shall meet the immunity pass/fail criteria determined by the manufacturer.