SLOVENSKI STANDARD
oSIST prEN ISO 14708-3:2015

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Vsadki (implantati) za kirurgijo - Aktivni medicinski pripomočki za vsaditev - 3. del: Vsadljivi nevrostimulatorji (ISO/DIS 14708-3:2015)

Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators (ISO/DIS 14708-3:2015)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 3: Implantierbare Neurostimulatoren (ISO/DIS 14708-3:2015)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 3: Neurostimulateurs en implant (ISO/DIS 14708-3:2015)

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ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

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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

ICS: 11.040.40

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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. 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. 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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL:

The committee responsible for this document is ISO/TC 150/SC 6.

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

ISO 14708 consists of the following parts, under the general title *Implants for surgery — Active implantable medical devices*:

— *Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

— *Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

— *Part 7: Particular requirements for cochlear implant systems*

Introduction

This part of ISO 14708 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 part of ISO 14708 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 part of ISO 14708 is intended to apply to these neurostimulator types regardless of therapy.

This part of ISO 14708 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 part of ISO 14708 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 part of ISO 14708.

“Addition”: the text of this part of ISO 14708 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 part ISO 14708.

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

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 part of ISO 14708 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 part of ISO 14708 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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/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.

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

[1] Second edition is under development.

Note 1 to entry For purposes of this part of ISO 14708, 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 (INS), consisting of a power source and electronic circuit, which produces a stimulation voltage or current pulse

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

Note 1 to entry Adapted from 3.1.11 of ASTM F2503.

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

3.105
DUT
device under test

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 whether 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; or

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 the following formula:

$$CEM43 = \sum_{i=1}^{n} t_i \cdot R^{(43-T)} \quad (1)$$

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.

This formula 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 labeled MR CONDITIONAL.

Implantable parts of an INS and any non-implantable components and accessories, which are labeled 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.

