SLOVENSKI STANDARD
oSIST prEN ISO 14708-4:2020

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Vsadki (implantati) za kirurgijo - Aktivni medicinski pripomočki za vsaditev - 4. del: Vsadljive infuzijske črpalke (ISO/DIS 14708-4:2020)

Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps (ISO/DIS 14708-4:2020)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 4: Implantierbare Infusionspumpen (ISO/DIS 14708-4:2020)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 4 : Systèmes de pompe à perfusion implantables (ISO/DIS 14708-4:2020)

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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 4:
Implantable infusion pump systems

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 4: Pompes d'infusion en implant

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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: Foreword - Supplementary information

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 14708-4:2008), which has been technically revised.

The main changes compared to the previous edition are as follows

— The title was modified,

— 9.4 additions deleted,

— 11.101 deleted,

— 14.2 replacement deleted,

— 14.101 deleted,

— 14.5 added,

— 17 revised,

— 19.2 replacement deleted,

— 19.3 replacement deleted,

— 19.101 deleted,

— 19.7 added,

— 23.2 amendment deleted,

— 27 revised,

— 28.8 additions deleted,

— 28.10 additions deleted,

— 28.12 addition deleted,

— 28.101 through 28.103 deleted,

— 28.31 and 28.31 added.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document specifies particular requirements for active implantable medical devices intended to deliver a medicinal substance to site-specific locations within the human body, to provide basic assurance of safety for both patients and users. It amends and supplements ISO 14708-1:2014. The requirements of document take priority over those of ISO 14708-1.

An *implantable infusion pump system* is a device that delivers either a constant flow rate or a variable flow rate from which a medicinal substance is delivered via an implanted catheter to site-specific locations within the human body. An external programmer might be used to adjust device parameters.

Requirements for physiologic sensing functions of *implantable infusion pump systems* are not included in this edition of this document but might be considered in future editions.

Annex A, Annex B and Annex C are provided for information only.

Implants for surgery — Active implantable medical devices —

Part 4: Implantable infusion pump systems

1 Scope

This document is applicable to active implantable medical devices intended to deliver medicinal substances to site-specific locations within the human body.

This document is also applicable to some non-implantable parts and accessories of the devices as defined in Clause 3.

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

NOTE This document is not intended to apply to non-implantable infusion systems.

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 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 10974:2018, *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+A1:2020, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — 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

3.1
bolus
specific amount of fluid (dose or volume) delivered once for a prescribed length of time (duration)

3.2
catheter access port
port allowing access to the delivery catheter

3.3
fluid pathway
internal surfaces of the *implantable infusion pump system* which are in direct contact with a medicinal substance

Note 1 to entry: Note to entry: This also includes catheters and refill kits.

3.4
implantable infusion pump system
active implantable medical device intended for delivery of a medicinal substance to a specific location within the human body

Note 1 to entry: Note to entry: For purposes of this document, an *implantable infusion pump system* can be a single article, or a set of components and accessories. Not all of these components or accessories might be required to be partially or totally implanted, e.g. programmers.

3.5
infusion accuracy
how close the true (actual) infusion rate is to the programmed rate

3.6
maximum rate
highest rate selectable by the user

3.7
minimum rate
lowest rate selectable by the user

3.8
MR Conditional
an item with demonstrated safety in the MR environment within defined conditions for the static magnetic field, the time-varying gradient magnetic field and the radiofrequency fields

[SOURCE: ASTM F2503-13, 3.1.11]

3.9
pump
implantable part of an *implantable infusion pump system* containing the fluid *reservoir*, energy source and, in some cases, control electronics

3.10
refill access port
port allowing access to the fluid *reservoir*

3.11
repeatability
ability to consistently deliver the same results over time, under the same conditions

Note 1 to entry: Note to entry: A method for calculating *repeatability* is given in Annex B of ISO 11631[1].

3.12
reservoir
a space designed to hold fluid

3.13
reservoir volume
fluid volume of the *reservoir* that can be discharged

3.14
service life
period after implantation when the *implantable infusion pump system* remains within stated specifications and characteristics

3.15
stability interval
calculated interval between two subsequent *reservoir* refills to assure stability of the medicinal substance

4 Symbols and abbreviated terms

The text in clause 4 of ISO 14708-1:2014 applies with the following addition:

DUT device under test

5 General requirements for active implantable medical devices

5.1 General requirements for non-implantable parts

The text in 5.1 of ISO 14708-1:2014 applies.

5.2 General requirements for software

The text in 5.2 of ISO 14708-1:2014 applies.

5.3 Usability of non-implantable parts

The text in 5.3 of ISO 14708-1:2014 applies.

5.4 Data security and protection from harm caused by unauthorized information tampering

The text in 5.4 of ISO 14708-1:2014 applies.

5.5 General requirements for risk management

The text in 5.5 of ISO 14708-1:2014 applies.

5.6 Misconnection of parts of the active implantable medical device

The text in 5.6 of ISO 14708-1:2014 applies.

6 Requirements for particular active implantable medical devices

6.1 Implantable infusion pump system specifications

The specifications (e.g. *infusion accuracy* and *repeatability*) stated by the manufacturer in the accompanying documentation (see 28.8) shall be maintained over the *service life* and over the range of environmental conditions and characteristics (e.g. *reservoir volume*) stated by the manufacturer.

NOTE Minimum environmental conditions for atmospheric pressure are specified in Clause 25.

Infusion accuracy shall be stated for all selectable rates (including *bolus* rates).

The manufacturer shall provide a plot of *infusion accuracy* versus environmental conditions and characteristics (e.g. *reservoir volume*) that affect *infusion accuracy*. For variable rate *implantable infusion pump systems*, the plot shall contain curves for *minimum rate*, *maximum rate*, and at least one rate in between the *minimum rate* and *maximum rate*.

The method of computing and determining the *infusion accuracy* shall be clearly stated in the accompanying documentation. Environmental test conditions used to establish *infusion accuracy* shall also be stated. Environmental conditions and characteristics that affect *infusion accuracy* shall be clearly stated in the accompanying documentation.

For all selectable infusion rates, the *repeatability* of the actual rate shall also be stated. The method of computing and determining the stated *repeatability* shall be clearly described in the accompanying documentation.

Compliance is checked by inspection of accompanying documentation and test procedures and reports, supported by the manufacturer's calculations, as appropriate.

6.2 Septum puncture test

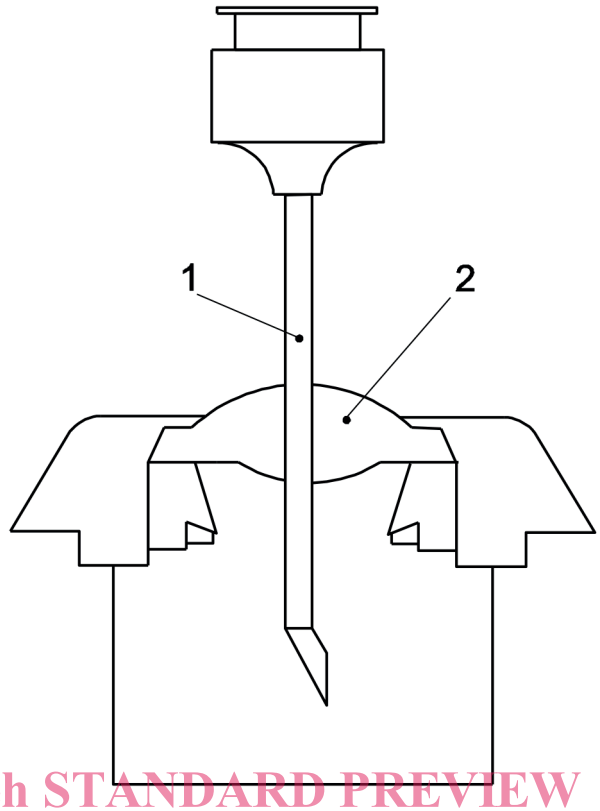
A septum that allows entry to an access port (e.g. *refill access port* or *catheter access port*), shall be able to withstand repeated insertions of a hypodermic needle while maintaining the integrity of the fluid *reservoir* throughout the *service life*.

Test: The DUT shall be conditioned at 37 °C ± 1 °C for not less than 12 h to achieve thermal equilibration. Each *pump* septum shall be punctured randomly using the needle specified by the manufacturer for septum puncture and in accordance with the manufacturer's instructions. The needle used for septum puncture shall be replaced if damage to the needle or the needle's tip is noted by the operator. The needle shall completely penetrate the septum and care should be taken not to damage the needle's tip during the test. Puncturing shall be done using a straight-line motion parallel to the septum's axial centre-line as shown in Figure 1.

Septum leakage shall be determined by immersing the test unit in a water bath at 37 °C ± 1 °C and allowing the temperature of the assembly to stabilize for a minimum of 30 min. Leakage shall be determined by air pressure applied slowly to a pressure of twice the *pump's* maximum operating pressure or a minimum of 276 kPa. The septum's exposed surfaces shall be examined for air bubble leakage for 1 min.

The maximum number of punctures for which the septum maintains integrity shall be stated (see 28.8).

Compliance is checked by inspection of accompanying documents and test reports.



Key

1 needle

2 septum

Figure 1 — Septum puncture test

7 General arrangement of the packaging

7.1 The text in 7.1 of ISO 14708-1:2014 applies.

7.2 The text in 7.2 of ISO 14708-1:2014 applies.

8 General markings for active implantable medical devices

8.1 The text in 8.1 of ISO 14708-1:2014 applies.

8.2 The text in 8.2 of ISO 14708-1:2014 applies.

8.3 If special handling measures have to be taken during transport, the shipping packaging shall be marked accordingly.

Compliance is checked by inspection.

8.4 The permissible environmental conditions for transport shall be marked on the outside of the shipping packaging (see ISO 15223-1[2]).

Compliance is checked by inspection.