INTERNATIONAL STANDARD

ISO 14708-4

Second edition
2022-02

Implants for surgery — Active implantable medical devices —

Part 4: Implantable infusion pump systems

Implants chirurgicaux — Dispositifs médicaux implantables actifs — Partie 4: Systèmes de pompe à perfusion implantables

Reference number
ISO 14708-4:2022(E)

© ISO 2022



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

© ISO 2022 – All rights reserved

Contents

Page

Foreword ..... **v**

Introduction ..... **vii**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Symbols and abbreviated terms **3**

5 General requirements for active implantable medical devices **3**
5.1 General requirements for non-implantable parts 3
5.2 General requirements for software 3
5.3 Usability of non-implantable parts 3
5.4 Data security and protection from harm caused by unauthorized information tampering 3
5.5 General requirements for risk management 3
5.6 Misconnection of parts of the active implantable medical device 3

6 Requirements for particular active implantable medical devices **3**
6.1 Implantable infusion pump system specifications 3
6.2 Septum puncture test 4

7 General arrangement of the packaging **5**

8 General markings for active implantable medical devices **5**

9 Markings on the sales packaging **6**

10 Construction of the sales packaging **6**

11 Markings on the sterile pack **7**

12 Construction of the non-reusable pack **7**

13 Markings on the active implantable medical device **7**

14 Protection from unintentional biological effects caused by the active implantable medical device **7**

15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device **8**

16 Protection from harm to the patient caused by electricity **8**

17 Protection from harm to the patient caused by heat **8**

18 Protection from ionizing radiation released or emitted from the active implantable medical device **9**

19 Protection from unintended effects caused by the active implantable medical device **9**

20 Protection of the active implantable medical device from damage caused by external defibrillators **10**

21 Protection of the active implantable medical device from changes caused by high-power electrical fields applied directly to the patient **10**

22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments **10**
22.1 Diagnostic ultrasound 10
22.2 Magnetic resonance imaging 10

23 Protection of the active implantable medical device from mechanical forces **11**

24 Protection of the active implantable medical device from damage caused by electrostatic discharge **12**

© ISO 2022 – All rights reserved

25 Protection of the active implantable medical device from damage caused by atmospheric pressure changes **12**

26 Protection of the active implantable medical device from damage caused by temperature changes **12**

27 Protection of the active implantable medical device from electromagnetic non-ionizing radiation **12**

27.1 General 12
27.2 Test conditions 13
27.2.1 Acceptance criteria 13
27.2.2 Test configuration 13
27.2.3 Operating functions, modes, and settings 13
27.3 Documentation 13
27.4 Protection from static magnetic fields of flux density up to 50 mT 14
27.5 Protection from magnetic fields over the frequency range 16 Hz to 26 MHz 15
27.6 Protection from EM disturbances over the frequency range 80 MHz to 2,7 GHz 16
27.7 Protection from proximity fields due to RF wireless communications equipment 17
27.8 Optional characterization testing 18

28 Accompanying documentation **18**

Annex A (informative) **Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this document** **21**

Annex B (informative) **Rationale** **42**

Annex C (informative) **Guidance on the allocation of requirements to non-implantable parts connected to a power source** **51**

Bibliography **58**

© ISO 2022 – All rights reserved

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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery,* SC 6, *Active implants,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/JTC 16, *Active implantable medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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 of this document has been modified;

— 9.4 additions have been deleted;

— 11.101 has been deleted;

— 14.2 replacement has been deleted;

— 14.101 has been deleted;

— 14.5 has been added;

— Clause 17 has been revised;

— 19.2 replacement has been deleted;

— 19.3 replacement has been deleted;

— 19.101 has been deleted;

— 19.7 has been added;

— 23.2 amendment has been deleted;

© ISO 2022 – All rights reserved

— Clause 27 has been revised;

— 28.8 additions have been deleted;

— 28.10 additions have been deleted;

— 28.12 addition has been deleted;

— 28.101 through 28.103 has been deleted;

— 28.31 and 28.32 has been 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.

© ISO 2022 – All rights reserved

Introduction

An *implantable infusion pump system* is a device that delivers either a constant infusion rate or a variable infusion 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.

© ISO 2022 – All rights reserved

Implants for surgery — Active implantable medical devices —

Part 4: Implantable infusion pump systems

1 Scope

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

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 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, *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, *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*

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

IEC 60601-1-2, *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, *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 terminology databases for use in standardization at the following addresses:

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

© ISO 2022 – All rights reserved

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

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* (3.4) which are in direct contact with a medicinal substance

Note 1 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: 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 rate accuracy
closeness of the true (actual) infusion rate to the programmed rate

3.6
maximum infusion rate
highest rate selectable by the user

3.7
minimum infusion rate
lowest rate selectable by the user

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

[SOURCE: ASTM F2503-20, 3.1.11]

3.9
pump
implantable part of an *implantable infusion pump system* (3.4) containing the *reservoir* (3.12), energy source and, in some cases, control electronics

3.10
refill access port
port allowing access to the *reservoir* (3.12)

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

Note 1 to entry: A method for calculating *repeatability* is given in Annex B of ISO 11631:1998.

© ISO 2022 – All rights reserved

3.12
reservoir
space designed to hold fluid

3.13
reservoir volume
fluid volume of the *reservoir* (3.12) that can be discharged

3.14
service life
period after implantation when the *implantable infusion pump system* (3.4) remains within stated specifications and characteristics

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 rate 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.

© ISO 2022 – All rights reserved